EXHIBIT 2

CT Corporation

Service of Process Transmittal
12/27/2018
CT Log Number 534641592

TO: Stephanie Youngman
Johnson & Johnson
1 Johnson and Johnson Plz
New Brunswick, NJ 08933-0002

RE: **Process Served in Virginia**

FOR: Depuy Synthes Sales, Inc. (Domestic State: MA)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Susan O. Cardoza, Pltf. vs. Medical Device Business Services, Inc., etc., et al., Dfts. // To: Depuy Synthes Sales, Inc.
DOCUMENT(S) SERVED:	Summons, Complaint, Exhibit(s)
COURT/AGENCY:	Danville City Circuit Courts, VA Case # 590CL1800085000
NATURE OF ACTION:	Product Liability Litigation - Personal Injury - Biolox
ON WHOM PROCESS WAS SERVED:	C T Corporation System, Glen Allen, VA
DATE AND HOUR OF SERVICE:	By Process Server on 12/27/2018 at 09:50
JURISDICTION SERVED :	Virginia
APPEARANCE OR ANSWER DUE:	Within 21 days after service
ATTORNEY(S) / SENDER(S):	Robert W. Mann Young, Haskins, Mann, Gregory, McGarry & Wall, P.C. Post Office Box 72 Martinsville, VA 24114-0072 276-638-2367
ACTION ITEMS:	CT has retained the current log, Retain Date: 12/27/2018, Expected Purge Date: 01/06/2019 Image SOP Email Notification, RA-JJCUS LDSOP RA-JJCUS-LDSOP@its.jnj.com
SIGNED:	C T Corporation System
ADDRESS:	4701 Cox Road Suite 285 Glen Allen, VA 23060
TELEPHONE:	804-217-7255

COMMONWEALTH OF VIRGINIA

DANVILLE CIRCUIT COURT
Civil Division
401 PATTON STREET PO BOX 3300
DANVILLE VA 24541
(434) 799-5168

Summons

To: DEPUY SYNTHES SALES, INC
CT CORP SYSTEM, REG AGENT
4701 COX ROAD
SUITE 285
GLEN ALLEN VA 23060

Case No. 590CL18000850-00

The party upon whom this summons and the attached complaint are served is hereby notified that unless within 21 days after such service, response is made by filing in the clerk's office of this court a pleading in writing, in proper legal form, the allegations and charges may be taken as admitted and the court may enter an order, judgment, or decree against such party either by default or after hearing evidence.

Appearance in person is not required by this summons.

Done in the name of the Commonwealth of Virginia on, Thursday, December 20, 2018

Clerk of Court: GERALD A. GIBSON

by _____
(CLERK/DEPUTY CLERK)

Instructions:

Hearing Official:

Attorney's name: MANN, ROBERT W; ESQ
400 STARLING AVE
P O BOX 72
MARTINSVILLE VA 24112-0072

VIRGINIA: IN THE CIRCUIT COURT FOR THE CITY OF DANVILLE

Susan O. Cardoza,

Plaintiff,

v.

Medical Device Business Services, Inc.
(Formally DePuy Orthopedics Inc.)
700 Orthopaedic Drive
Warsaw, IN 46581

and

Johnson & Johnson Services, Inc.
(Johnson & Johnson)
One Johnson & Johnson PLZ
New Brunswick, NJ 08933

and

DePuy Synthes Sales, Inc.
325 Paramount Drive
Raynham, MA 02767

and

CeramTec GmbH
CeramTec – Platz 1-9
73207, Plochingen
Germany

and

CeramTec North American Corp.
CeramTec Subsidiary, American Headquarters
One Technology Place
Laurens, SC 29360

and

Danville Regional Medical Center, LLC
(d/b/a SOVAH Danville)
103 Powell Ct., Ste 200
Brentwood, TN 37027

FIRST INTERROGATORIES, REQUESTS FOR PRODUCTION OF DOCUMENTS, AND REQUESTS FOR ADMISSIONS TO DEPUY DEFENDANTS
Case No. CL18000850-00

Law Offices
Young, Haskins, Mann,
Gregory, McGarry
& Wall, P.C.
Martinsville, VA

and

Spectrum Medical Inc.
109 Bridge Street, Suite 300
Danville, VA 24541

and

Matt Wimbish
Roanoke, Virginia

Defendants

PLAINTIFF'S FIRST SET OF INTERROGATORIES, REQUESTS FOR PRODUCTIONOF DOCUMENTS AND REQUESTS FOR ADMISSIONS TO MEDICAL DEVICE BUSINESS SERVICES, INC., JOHNSON & JOHNSON SERVICES, INC., AND DEPUY SYNTHES SALES, INC.

NOW COMES Plaintiff, Susan O. Cardoza, by counsel, pursuant to Rules 4:8, 4:9 and 4:11 of the Rules of the Supreme Court of Virginia, and propounds the following discovery to the captioned Defendants: Medical Device Business Services, Inc., Johnson & Johnson Services, Inc. and DePuy Synthes Sales, Inc.

DEFINITIONS

To facilitate your answers to this discovery, the terms used herein have the following meanings unless the context requires otherwise.

1. "The product" refers to CERAMAX Ceramic Total Hip System (containing Biolox Delta), more specifically described and identified in the product labeling or product "stickers" attached as Exhibit A to the Complaint filed herein.
2. The "incident in question" refers to the failure of Ms. Cardoza's prosthetic hip which was implanted in her body December 15, 2016.
3. "Explanted liner components" refers to the fractured ceramic liner pieces removed from Ms. Cardoza's body at the time of revision surgery, March 10, 2017. "Explanted head"

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Martinsville, VA

refers to the ceramic head removed from Ms. Cardoza's body at the time of revision surgery, March 10, 2017.

4. "You" or "your" or "DePuy" refers to Medical Device Business Services Inc. (Formally DePuy Orthopedics Inc.), Johnson & Johnson Services Inc., and DePuy Synthes Sales Inc., its successors, predecessors, agents and employees and all other persons acting on behalf of said defendants.

5. "Documents"" or "writings of every kind and description" means all written, typed or printed matter and all magnetic or other records or documentation of any kind or description (including, without limitations, letters, correspondence, telegrams, memoranda, notes, records, minutes, contracts, agreements, records or notations of telephone or personal conversations, conferences, interoffice communications, microfilm, bulletins, circulars, pamphlets, photographs, artists' renderings, invoices, tape recordings, computer printouts and work sheets), including, drafts and copies not identical to the originals, all photographs and graphic matter, however produced or reproduced, and all compilations of data from which information can be obtained, and any and all writings or recordings of any type or nature in your actual or constructive possession, custody or control, including those in the possession, custody or control of any and all present or former directors, officers, employees, consultants, accountants, attorneys or other agents, whether or not prepared by you.

6. "Report" means the results of any examination, inspection, testing, or audits performed by the DePuy defendants, or at the direction and request of DePuy defendants by others.

7. The words "describe" or "identify" when referring to a person are meant to request that you set forth the following information: (a) Full name. (b) Present or last known residential address. (c) Present or last known telephone number. (d) Present occupation, job title, employer and employer's address. (e) Occupation, job title, employer and

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employer's address at the time of the event or period referred to in each particular Interrogatory. (f) In the case of any person other than an individual, identification of the officer, employee or agent most closely connected with the subject matter of that Interrogatory and of the officer who is responsible for supervising that officer or employee with regard to the subject matter of that Interrogatory.

8. The words "describe" or "identify" when referring to a document, are meant to request that you set forth the following information: (a) The nature (*e.g.*, letter, handwritten note) of the document. (b) The title or heading that appears on the document. (c) The date of the document and the date of each addendum, supplement or other addition or change. (d) Identification of the author and of the signor thereof, and of the person on whose behalf or at whose request or direction the document was prepared or delivered. (e) Identification of the addressee or recipient thereof, if any. (f) The present location of the document, and the name, address, position or title and telephone number of the person or persons having custody.

INTERROGATORIES

1. Identify the person(s) signing and verifying your answers to this discovery. Identify all persons who were contacted in order to answer to this discovery. Identify DePuy's most knowledgeable person regarding the investigation into your complaint file COM-27-588 and the incident in question. Indentify DePuy's most knowledgeable person regarding the chain of custody for the explanted liner component.

ANSWER:

2. Identify all persons involved in the chain of custody pertaining to the Plaintiff's explanted liner components; and, describe any and all precautions used to assure the safety, security and integrity of the explanted liner components. This question is

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intended for you to disclose, in detail, all circumstances regarding possession and handling of the explanted liner components from the time said components left the surgical tray at the Danville hospital on March 10, 2017 until the time said components were sent to 400 Starling Avenue, Martinsville, Virginia by FedEx on November 21, 2018. Include any and all accidental breakage or damage to the explanted liner components after said components came into the possession of Mr. Wimbish.

ANSWER:

3. How many pieces were there of the explanted liner components when Mr. Wimbish took possession of said components at the Danville hospital. How many pieces of the explanted liner components were placed in the FedEx shipment sent to 400 Starling Avenue, Martinsville, Virginia on November 21, 2018? Indentify and describe all documents and writings of every kind and description in support of your answer.

ANSWER:

4. Indentify and describe, with particularity, all examination, inspections, and testing of the explanted liner components including, but not limited to, all testing to determine hardness, elasticity, and propensity to fracture or break.

ANSWER:

5. Indentify and describe, with particularity, all inspection, examination, and testing of the explanted liner components which was specifically done in an effort to determine the root cause of fracture of the explanted liner component in Ms. Cardoza's hip.

ANSWER:

6. Indentify and describe, with particularity, all inspection, examination, testing, and analysis specifically done to determine whether the explanted liner component was manufactured in compliance with the FDA approved protocol for this product.

ANSWER:

7. Indentify and describe, with particularity, any destructive testing done on the explanted liner component. Include, but do not limit your answer to, any and all chemical analysis for inclusions; any and all chemicals used to sanitize the explanted liner component; and all other chemical or physical alterations of the explanted liner components. How did you assure that there was no deleterious effect as a result of your procedures and analysis?

ANSWER:

8. What is the last known address of Matthew (Matt) Wimbish? Indentify and describe his employment or agency responsibilities with DePuy.

ANSWER:

9. Indentify and describe, with particularity, when, where, and under what circumstances Mr. Wimbish originally took possession of the fractured explanted liner components.

ANSWER:

10. Indentify and describe, with particularity, all witnesses to Mr. Wimbish having assumed possession of the explanted liner components. Indentify all documents, or paper trail pertaining to this acquisition including, but not limited to, Mr. Wimbish's notes and/or reports.

ANSWER:

11. Indentify and describe, with particularity, when, where, and under what circumstances you acquired Ms. Cardoza's medical records. Indentify all witnesses to this acquisition. Indentify all documents, or paper trail pertaining to this acquisition.

ANSWER:

12. Indentify and describe, with particularity, the root cause of Ms. Cardoza's ceramic

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liner failure and the underlying reasons and contributing causes for such failure. Indentify any documents wherever you referred to attempts to determine the root cause.

ANSWER:

13. State whether or not, as a result of the incident in question, there was any corrective action, recommendations or suggestions with regard to manufacture, sale, and/or repossession of ceramic liner components. If so, identify and explain.

ANSWER:

14. If you contend that Ms. Cardoza, or any third party, caused or significantly contributed to the fracture and failure of the ceramic liner, identify the individual and company and set forth the complete basis for your contention.

ANSWER:

15. Prior to receiving notification of representation from undersigned counsel, sent October 10, 2018 (See Exhibit A), state whether or not your file and investigation of Ms. Cardoza's explanted liner component and the incident in question had been completed and closed. If not, what remained to be done? Explain why there had been no previous response to the repeated requests made by Mr. Simmons. (See Exhibit A)

ANSWER:

16. Indentify and describe, with particularity, your quality assurance protocol to assure compliance with FDA PMA approval. Include, but do not limit your answer to, process controls on raw materials or other materials received from CeramTec or others. Include, but do not limit your answer to, protocols with respect to insuring proper hardness, appropriate elasticity, and minimizing propensity for breakage and fracture.

ANSWER:

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17. In connection with your examination, inspection, and testing of the explanted liner components, was any failure analysis performed? If so, what was specifically done and what were the conclusions? For example: (a) Were the components analyzed to assure its composition and microstructure complied with design specifications? If so, explain. (b) Were the liner components assessed in any way to assure compliance with design specifications for strength, toughness, hardness, wear resistance, and propensity to breakage or fracture? If so, explain. (c) Were the fracture surfaces of the explanted liner components examined to determine if the material had defects that could act as stress raisers? If so, explain.

ANSWER:

18. Indentify and describe, all internal and external audits pertaining to the relevant lots from which Ms. Cardoza's prosthesis was produced.

ANSWER:

19. Indentify and describe, all complaints known to you pertaining to the CERAMAX Ceramic Total Hip System (containing Biolox Delta) from 2000 to the present. Include, but do not limit your description to, whether or not the complaints related to fracture of the ceramic liner.

ANSWER:

20. Indentify and describe, by date, jurisdiction, court, and attorneys and deposition all lawsuits against you from the year 2000 to the present pertaining to alleged defects in the CERAMAX Ceramic Total Hip System (containing Biolox Delta).

ANSWER:

21. If your response to any of the following request for admissions is anything other than an unqualified admission, state in detail and explain the basis for your response and identify all witnesses and documentation which justify your refusal to admit.

ANSWER:

Requests For Production Of Documents

1. Produce DePuy's file pertaining to case COM-27-588, omitting nothing.

RESPONSE:

2. Produce all documents and correspondence, of every kind and description, pertaining to the incident in question. Include, but do not limit your answer to, all correspondence to and from:

a. Other defendants in this lawsuit

b. FDA

c. Internal correspondence

d. Outside consultants

RESPONSE:

3. Produce all reports, memorandums, results, or analysis pertaining to all testing, examination, and inspection of Ms. Cardoza's explanted liner components.

RESPONSE:

4. Produce all findings and non-compliance reports from internal and external audits regarding the lots involved in interrogatory 18.

RESPONSE:

5. Produce your file (personnel file or the like) for Matthew (Matt) Wimbish.

RESPONSE:

6. Produce all writings, of every kind and description, authored or made by Mr. Wimbish in connection with the incident in question.

RESPONSE:

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7. Produce all writings, of every kind and description, sent to Mr. Wimbish by employees or agents of any of the DePuy or J&J defendants in connection with the incident in question.

RESPONSE:

8. Produce any notice letters, correspondence, or writings, of every kind and description, to and from any of the DePuy/J&J defendants and to and from the CeramTec defendants.

RESPONSE:

9. Produce all micrographs, and imaging, of every kind and description, done in connection with investigation, examination and testing of the explanted liner components. Include all indentifying data pertaining to the imaging produced.

RESPONSE:

10. Produce all of your policies, protocols, or procedures pertaining to repossession or taking possession of explanted prosthesis after revision surgery.

RESPONSE:

11. Produce all policies, procedures, or protocols concerning compliance with FDA approved requirements for the products.

REPONSE:

12. Produce a Privilege Log pursuant to Virginia Code § 4:1 (a) (6) (i) indentifying any information, or requested information, in this discovery for which you claim privilege.

RESPONSE:

13. Produce all documentation in support of your conclusion or assertion in Exhibit A (Hahn letter) that Ms. Cardoza's implanted hip was not defective in any way.

RESPONSE:

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14. Produce all documents and correspondence, of every kind and description, concerning or pertaining in any way to your attempts to acquire, and acquiring, Ms. Cardoza's medical records.

RESPONSE:

15. Produce all documents and correspondence, of every kind and description, concerning or pertaining in any way to your attempts to acquire, and acquiring, Ms. Cardoza's explanted head.

RESPONSE:

16. Produce all documents and correspondence, of every kind and description, concerning or pertaining in any way to your attempts to acquire, and acquiring, Ms. Cardoza's explanted liner components.

RESPONSE:

17. Produce all documents, related to or in any way concerning the chain of custody of the explanted liner components.

RESPONSE:

18. Produce all documents indentified in answers to the preceding interrogatories and/or consulted, used, and/or relied upon in preparing answers to this discovery.

RESPONSE:

Requests For Admissions

1. Admit the authenticity and genuineness of correspondence in Exhibit A between agents for DePuy and agents for Ms. Cardoza.

RESPONSE:

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& Wall, P.C.
Martinsville, VA

2. Admit that, prior to and on the date of the incident in question, it was the custom and practice of DePuy to take possession if possible, or at least seek possession, of all failed implants after revision surgery.

REPSONSE:

3. Admit that, in the past, in keeping with the aforesaid practice DePuy has compensated surgeons financially for acquiring the patient's consent and authorization to release explanted components to DePuy.

RESPONSE:

4. Admit that your acquisition, possession of, and testing of the explanted components was I the ordinary course of business.

REPSONSE:

5. Admit that your acquisition, possession of, and analysis of Ms. Cardoza's medical records was in the ordinary course of business.

REPONSE:

6. Admit that your creation and maintenance of Complaint File COM-27-588 was in the ordinary course of business.

RESPONSE:

7. Admit that, neither DePuy, nor Mr. Wimbish, had Ms. Cardoza's permission, consent, or authorization for you to take possession of her explanted component(s).

RESPONSE:

8. Admit that, when Mr. Wimbish took possession of Ms. Cardoza's explanted component(s), he was acting in furtherance of DePuy's ends, and had no independent personal motive of his own.

REPSONSE:

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& Wall, P.C.
Martinsville, VA

9. Admit that, in connection with the incident in question, Mr. Wimbish was DePuy's agent and acting within the scope of his authority and agency.

REPSONSE:

10. Admit that, at all pertinent times, you knew that you did not have Ms. Cardoza's authorization, permission, or consent to possess and exercise dominion over her explanted hip component.

RESPONSE:

11. Admit that, at all pertinent times, you knew that it was improper and unlawful to possess and exercise dominion over Ms. Cardoza's explanted hip without her authorization, permission, and consent.

RESPONSE:

12. Admit that, at all pertinent times, you knew that you did not have Ms. Cardoza's authorization, permission, or consent to possess and exercise dominion over her medical records.

RESPONSE:

13. Admit that, it is unlikely that Ms. Cardoza's ceramic hip implant would have fractured, in separate pieces, in less than three months of implantation, as in this case, if FDA approved protocols and requirements had been followed.

RESPONSE:

14. Admit that, at all pertinent times, you knew that it was improper and unlawful to possess and exercise dominion over Ms. Cardoza's medical records without her authorization, permission, and consent.

RESPONSE:

Respectfully submitted,

SUSAN O. CARDOZA

By: _____
Of Counsel

Robert W. Mann, Esquire (VSB #07622)
YOUNG, HASKINS, MANN, GREGORY, MCGARRY & WALL, P.C.
Post Office Box 72
Martinsville, VA 24114-0072
Telephone (276)-638-2367
Facsimile (276)-638-1214
Email: RWMann@comcast.net

CERTIFICATE OF SERVICE

I certify that a true and exact copy of the foregoing Plaintiff's First Set of Interrogatories, Requests for Production of Documents and Requests for Admissions was sent by first class mail, postage fully pre-paid, to William A. Hahn, II, Esquire, 11 South Meridian Street, Indianapolis, IN 46204-3535, attorney for DePuy and J&J defendants; Ashley Calkins, Esquire, P.O. Box 72050, Richmond, Virginia 23255-2050 attorney for Danville Regional Medical Center LLC; Spectrum Medical Inc., 109 Bridge St., Suite 300, Danville, Virginia, 24541 and CeramTec GmbH, CeramTec-Platz 1-9, 73207, Plochingen, Germany, on this 19th day of December 2018 to:

_____
Robert W. Mann

EXHIBIT A INDEX

Description	Bates#
Preservation Letter to DePuy (04/18/2017)	001
Letter to Mr. Hahn (07/24/2017)	002
Letter to Mr. Hahn (11/06/2017)	003
Letter to Mr. Hahn (02/05/2018)	004
Letter to Mr. Hahn (10/10/2018)	005
Mr. Hahn letter to Mr. Mann (11/14/2018)	006
Email to Mr. Hahn from Mr. Mann (11/19/2018)	007

LUIS A. ABREU, PLLC

ATTORNEYS AT LAW

Luis A. Abreu
labreu@luisabreulaw.com

Michael D. Simmons
msimmons@luisabreulaw.com

P. O. Box 1598
626 North Ridge Street
Danville, Virginia 24543
www.luisabreulaw.com

(434) 791-4677
Fax: (434) 791-4676

April 18, 2017

VIA Certified Mail, Return Receipt Requested, and Electronic Transmission

DePuy Synthes Joint Reconstruction
700 Orthopaedic Drive
Warsaw, IN 46582

Preservation of Evidence/ Spoliation Notice

RE:	Our Client:	Susan Olival Cardoza
	Address:	172 Graymont Place Danville, VA 24541
	Date of Birth:	12/19/1953
	Social Security #:	###-##-0687

Dear Sir/Madam:

Please be advised that we represent Susan Cardoza with respect to her injuries sustained from a failed hip replacement performed on December 15, 2016. It is requested that you provide us with a complete copy of your file regarding services or products rendered to Ms. Cardoza. Please also provide us with copies of all documentation relating to the hip replacement and parts used in the hip replacement surgery.

This letter is to also put DePuy Synthes on notice that it must preserve all data of any type relating to the claim. Most importantly, all of the hip replacement parts removed during the operation must be preserved. This includes, without limitation, the CERAMAX Ceramic Insert, BIOLOX Delta Ceramic Femoral Head, and any other part that was replaced on March 10, 2017. We have attempted to contact your employee, Richard Fox with Quality Control, whose name was given to us by the office of the treating physician, Dr. Mark C. Hermann. We were notified by Dr. Hermann's office that Mr. Fox had the pieces described above. We were advised that the Case Number is COM-271-588 and the phone number provided to us for Mr. Fox is 1-866-811-9367. We have left several messages at that phone number but have not received any response or call backs, and we are attempting to notify Mr. Fox and DePuy that any and all parts of the hip replacement removed from Ms. Cardoza's hip after the surgery are to be preserved. Please ensure this letter is provided to the appropriate person in your office who is charged with the custody of the above items.

Please do not dispose of any of this material, as I expect that it will be both discoverable and admissible in any litigation that may arise out of this claim. Failure to preserve this material will result in a request for a spoliation instruction at any trial in this matter.

001

LUIS A. ABREU
ATTORNEY AT LAW

If you are no longer in possession of these parts, please identify who has or took these parts (and their contact information). Please also share the circumstances under which the parts were removed during the second surgery.

Thank you for your assistance in this matter. If you have any questions, please do not hesitate to call us at 434-791-4677 during regular business hours.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan Olival Cardoza (VIA Electronic Transmission and U.S. Mail)

Mark C. Hermann, M.D. (VIA U.S. Mail)

LUIS A. ABREU, PLLC

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labreu@luisabreulaw.com

Michael D. Simmons
msimmons@luisabreulaw.com

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July 24, 2017

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

William A. Hahn, II, Esq.
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204-3535

RE: Our Client: Susan Olival Cardoza

Dear Mr. Hahn:

As you may recall, our firm contacted you about Ms. Susan Cardoza's hip replacement parts that were taken by a DePuy representative and subsequently shipped to the U.K. We have not heard from you since May 5, 2017. We are requesting an update on those parts and any relevant information you may have. It is our belief that any testing by DePuy should have been completed by this time and progress in the analysis of the parts should be well under way.

Please update us as soon as possible. We look forward to hearing from you. If you have any questions, please call us at 434-791-4677.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan O. Cardoza (VIA Electronic Transmission and U.S. Mail)

002

LUIS A. ABREU, PLLC

ATTORNEYS AT LAW

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November 6, 2017

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

William A. Hahn, II, Esq.
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204-3535

RE: Our Client: Susan Olival Cardoza

Dear Mr. Hahn:

As you may recall, our firm represents Ms. Susan Cardoza in connection with the injuries she sustained when her total hip replacement surgery in December of 2016 failed. We have not heard from you since May 5, 2017, regarding the removed parts that were sent to the United Kingdom for testing, although we have requested an update on multiple occasions. Please update us as soon as possible, since we need to move forward. In addition, we are requesting that the removed parts be made available to us, or a representative on our behalf, so that we may make an independent evaluation of those parts. Furthermore, we remind you that all the parts need to be preserved as evidence.

Please update us as soon as possible. We look forward to hearing from you. If you have any questions, please call us at 434-791-4677.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan O. Cardoza (VIA Electronic Transmission and U.S. Mail)

LUIS A. ABREU, PLLC

ATTORNEYS AT LAW

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February 5, 2018

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

William A. Hahn, II, Esq.
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204-3535

RE: Our Client: Susan Olival Cardoza

Dear Mr. Hahn:

As you may recall, we represent Ms. Susan Cardoza in the injuries she sustained when her total hip replacement failed. The purpose of this letter is to give you the opportunity to share with us the reason(s) for the failure of the hip replacement parts. Ms. Cardoza's medical records do not expound upon the reason(s) for the failure, and if you are aware of whether it was a manufacturing defect(s), an incorrect installation, or other error, we hope that you would share with us your position as to any reasons her first two operations were not successful.

Finally, we remind you that all the evidence in this matter must be preserved.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan Olival Cardoza
(VIA Electronic Transmission and U.S. Mail)

LAW OFFICES

YOUNG, HASKINS, MANN, GREGORY, McGARRY & WALL

A PROFESSIONAL CORPORATION

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ROBERT W. MANN*
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R.R. (JIM) YOUNG, JR.
(1922-1995)

PHONE (276) 638-2367
FAX (276) 638-1214

October 10, 2018

Certified Mail Return Receipt Letter
William A. Hahn II, Esquire
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204

RE: *DePuy case number: COM-271-588*
*Susan Cardoza, DOB: 12/19/1953, SSN: ***-**-0687*

Dear Mr. Hahn:

We are associated with Luis A. Abreu and Michael D. Simmons representing Ms. Cardoza. We have been retained to file suit in this matter. I am enclosing an updated HIPPA authorization and request.

I am also enclosing the initial notice letter and request dated April 18, 2017, along with self-explanatory correspondence dated July 24, 2017, November 6, 2017, and February 5, 2018. It is my understanding there has been no response.

It is apparent that DePuy took possession of the failed implant on the date of Ms. Cardoza's revision surgery, March 10, 2017. It is our understanding that DePuy subsequently conducted an investigation and appropriate testing to determine the root cause of failure. We assume that an appropriate Medical Device Report was filed with the FDA as required by law. In addition to the information previously requested, this request is for all communications relative to this matter between DePuy and the FDA.

Time is of extreme essence. The applicable statute of limitations requires that appropriate action must be filed on or before December 15, 2018. Accordingly, please let me hear from you at your very first convenience.

Very truly yours,

Robert W. Mann

RWM/hmb
Enclosures
Cc: Michael D. Simmons, Esquire
Luis Abreu, Esquire

*CERTIFIED SPECIALIST IN CIVIL TRIAL ADVOCACY BY THE NATIONAL BOARD OF TRIAL ADVOCACY
THERE IS NO PROCEDURE IN THE COMMONWEALTH OF VIRGINIA FOR APPROVING CERTIFYING ORGANIZATIONS

BARNES & THORNBURG LLP

11 S. Meridian Street
Indianapolis, IN 46204-3535
317-236-1313
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William A. Hahn
Partner
(317) 231-7364
william.hahn@btlaw.com

November 14, 2018

Via United States First Class Mail

Robert W. Mann
Young, Haskins, Mann, Gregory,
McGarry & Wall, PC
400 Starling Ave.
Martinsville, VA 24112

Re: *Susan Cardoza – Claim Regarding Pinnacle Acetabular Cup System*

Dear Mr. Mann:

Thank you for allowing us the opportunity to review the medical records and explant relating to your client Susan Cardoza's claim. The examination of these materials does not indicate that any DePuy products that were implanted in her hip were defective in any respect. Accordingly, DePuy respectfully declines your client's claim.

The records we have received indicate that Ms. Cardoza had a left hip total replacement in 2013. We have received no records relating to that procedure. On June 1, 2016, Ms. Cardoza treated with Dr. Mark Hermann with reports of both right knee and right hip pain. Dr. Hermann diagnosed her with having early osteoarthritis in her right hip. At that time, Dr. Hermann did not recommend a hip replacement procedure due to the early nature of her osteoarthritis. On September 19, 2016, Ms. Cardoza had a follow up with Dr. Hermann at which time she was reporting pain in both her right knee and right hip. Dr. Hermann scheduled her for a follow up appointment to discuss timing of a surgical intervention. On November 11, 2016, she again saw Dr. Hermann to discuss her total hip replacement surgery. At that time, risks and benefits of the procedure were discussed with Ms. Cardoza.

Dr. Hermann performed her right total hip replacement surgery on December 15, 2016. Dr. Hermann elected to utilize a ceramic insert with a ceramic femoral head. We have not received any product stickers for the products Dr. Hermann elected to implant. We also have not received any records identifying the femoral stem or acetabular cup that Dr. Hermann implanted.

Ms. Cardoza had a follow up with Dr. Hermann on December 27, 2016, at which time he noted that she was reporting no difficulties. On March 1, 2017, Ms. Cardoza had another follow up with Dr. Hermann relating to her right hip arthroplasty. At that time, she reported a "crunchy" sensation with an audible noise while bending. She reported that it was not painful. Dr. Hermann examined her and confirmed an audible crunching sound while flexing her hip for

squats. Dr. Hermann determined that he wanted to evaluate her x-rays and recheck her in two weeks. On March 7, 2017, Dr. Hermann saw her again and determined that Ms. Cardoza had sustained a fractured ceramic liner.

Dr. Hermann performed a revision procedure on March 10, 2017. Dr. Hermann noted that the hip fluid he encountered was normal. Dr. Hermann confirmed that the ceramic liner had fractured. He removed the fractured components and the ceramic head. He elected to implant a polyethylene liner and a metal femoral head. We do not have product stickers for the components Dr. Hermann implanted during the revision procedure. Ms. Cardoza saw Dr. Hermann for a follow up appointment on March 23, 2017, at which time he noted that Ms. Cardoza was feeling much better.

With regard to Ms. Cardoza's ceramic insert, DePuy has not identified any anomalies or material defects regarding the insert. Nor were any issues identified with respect to the lot from which the insert came.

Based on the investigation to date, there is nothing demonstrating that any DePuy products implanted during Ms. Cardoza's total hip replacement on her right hip were defective in any respect. Accordingly, DePuy respectfully declines your client's request for compensation. We appreciate your cooperation in allowing us the opportunity to investigate Ms. Cardoza's claim, and extend sincere wishes for her good health in the future. Lastly, please let me know where you would like to have the ceramic insert sent to.

Very truly yours,

William A. Hahn

WAH:alw

Robert W. Mann

From: Robert W. Mann [RWMann@comcast.net]
Sent: Monday, November 19, 2018 3:03 PM
To: 'william.hahn@btlaw.com'
Subject: Susan Cardoza

Dear Mr. Hahn:

I am receipt of your letter dated November 14, 2018, received in today's mail November 19th, 2018. As we discussed on October 30, 2018, we requested that the failed ceramic insert be sent to me at 400 Starling Avenue, Martinsville VA 24112. Of course, assuring the chain of custody is your responsibility. As you know from previous correspondence, as well as our conversation on October 30th , time is of the essence as the applicable statute of limitations runs December 14, 2018.

Your November 14th letter opens and closes with the conclusion that the product was not "defective in any respect". You provide no explanation or basis for this conclusion. DePuy's manufacturing representative ,Matthew Wimbish, without Ms. Cardoza's permission, took possession of the fractured implant on March 10, 2017. So far as we can determine, neither the hospital nor the surgeon purported to give any permission to Mr. Wimbish. That said, the implant belonged to Ms. Cardoza, not the hospital or the surgeon. Under these circumstances, there is at least an implied promise that, in return for DePuy having had the failed product for a year and eight months, DePuy would release to Ms. Cardoza the specifics of any testing done which may have led to the conclusion that the product was not "defective in any respect". Further, I note that your Medical Device Report to the FDA states that the matter is still under investigation, and this has not been finally updated.

In addition to relinquishing physical possession of the fractured implant, we again call on DePuy to provide us with a description of all of the tests done on the failed product; the specific test results; including, but not limited to, raw data. This is essentially the same request that was made by Ms. Cardoza in DePuy's initial notice latter dated April 18,2017. I reiterate, time is of the essence. Please let me have your client's position on this request as soon as possible.

Robert W. Mann
Young, Haskins, Mann, Gregory, McGarry & Wall, PC
400 Starling Ave.
Martinsville, VA 24112
(276) 638-2367 (telephone)
(276) 638-1214 (facsimile)

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OCT 11 2018

Sent To William A. Hahn II, Esq.
Barnes + Thornburg LLP
Street, Apt. No.; or PO Box No. 11 South Meridian Street
City, State, ZIP+4 Indianapolis, IN 46204
PS Form 3800, August 2006 See Reverse for Instructions

7010 2780 0003 5272 9078

PLACE STICKER AT TOP OF ENVELOPE

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- Complete items 1, 2, and 3.
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William A. Hahn II, Esquire
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204

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2. Article Number (Transfer from service label)
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A. Signature
X Ed Maggitt
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☑ Addressee

B. Received by (Printed Name) Ed Maggitt
C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes
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☐ Registered Mail Restricted Delivery
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PS Form 3811, July 2015 PSN 7530-02-000-9053 Domestic Return Receipt

005

CT Corporation

Service of Process Transmittal
12/27/2018
CT Log Number 534645632

TO: Stephanie Youngman
Johnson & Johnson
1 Johnson and Johnson Plz
New Brunswick, NJ 08933-0002

RE: **Process Served in Virginia**

FOR: Johnson & Johnson Services, Inc. (Domestic State: NJ)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Susan O. Cardoza, Pltf. vs. Medical Device Business Services, Inc., etc., et al., Dfts. // To: Johnson & Johnson Services, Inc.
DOCUMENT(S) SERVED:	Summons, Complaint, Exhibit(s), First Set of Interrogatories, Letter(s), Request(s)
COURT/AGENCY:	Danville County Circuit Court, VA Case # 590CL1800085000
NATURE OF ACTION:	Product Liability Litigation - Personal Injury - Cermax Ceramic Total Hip System
ON WHOM PROCESS WAS SERVED:	C T Corporation System, Glen Allen, VA
DATE AND HOUR OF SERVICE:	By Process Server on 12/27/2018 at 09:50
JURISDICTION SERVED :	Virginia
APPEARANCE OR ANSWER DUE:	Within 21 days after such service (Document(s) may contain additional answer dates)
ATTORNEY(S) / SENDER(S):	Robert Mann Young, Haskins, Mann, Gregory, Mcgarry & Wall, P.C. 400 Starling Ave PO BOX 7247 Martinsville, VA 24112-0072 (276)-638-2367
ACTION ITEMS:	CT has retained the current log, Retain Date: 12/31/2018, Expected Purge Date: 01/05/2019 Image SOP Email Notification, RA-JJCUS LDSOP RA-JJCUS-LDSOP@its.jnj.com Email Notification, Amy McLaren cls-ctsopsupport@wolterskluwer.com
SIGNED:	C T Corporation System
ADDRESS:	4701 Cox Road Suite 285 Glen Allen, VA 23060
TELEPHONE:	804-217-7255

COMMONWEALTH OF VIRGINIA

DANVILLE CIRCUIT COURT
Civil Division
401 PATTON STREET PO BOX 3300
DANVILLE VA 24541
(434) 799-5168

Summons

To: JOHNSON& JOHNSON
SERVICES, INC
CT CORP SYSTEM, REG AGENT
4701 COX ROAD
SUITE 285
GLEN ALLEN VA 23060

Case No. 590CL18000850-00

The party upon whom this summons and the attached complaint are served is hereby notified that unless within 21 days after such service, response is made by filing in the clerk's office of this court a pleading in writing, in proper legal form, the allegations and charges may be taken as admitted and the court may enter an order, judgment, or decree against such party either by default or after hearing evidence.

Appearance in person is not required by this summons.

Done in the name of the Commonwealth of Virginia on, Thursday, December 20, 2018

Clerk of Court: GERALD A. GIBSON

by _____
(CLERK/DEPUTY CLERK)

Instructions:

Hearing Official:

Attorney's name: MANN, ROBERT W; ESQ
400 STARLING AVE
P O BOX 72
MARTINSVILLE VA 24112-0072

VIRGINIA: IN THE CIRCUIT COURT FOR THE CITY OF DANVILLE

Susan O. Cardoza,

Plaintiff,

v.

Medical Device Business Services, Inc.
(Formally DePuy Orthopedics Inc.)
700 Orthopaedic Drive
Warsaw, IN 46581

and

Johnson & Johnson Services, Inc.
(Johnson & Johnson)
One Johnson & Johnson PLZ
New Brunswick, NJ 08933
and

DePuy Synthes Sales, Inc.
325 Paramount Drive
Raynham, MA 02767

and

CeramTec GmbH
CeramTec – Platz 1-9
73207, Plochingen
Germany

and

CeramTec North American Corp.
CeramTec Subsidiary, American Headquarters
One Technology Place
Laurens, SC 29360

and

Danville Regional Medical Center, LLC
(d/b/a SOVAH Danville)
103 Powell Ct., Ste 200
Brentwood, TN 37027

and

COMPLAINT
Case No. CL18-850

FILED
2018 DEC 13 PM 12:00
CLERK'S OFFICE
CIRCUIT COURT
DANVILLE, VIRGINIA

LAW OFFICES
YOUNG, HASKINS, MANN,
GREGORY, MCGARRY
& WALL, P.C.
MARTINSVILLE, VA

Spectrum Medical Inc.
109 Bridge Street, Suite 300
Danville, VA 24541

and

Matt Wimbish
Roanoke, Virginia

Defendants

COMES NOW the Plaintiff, Susan Olival Cardoza, by counsel, and respectfully alleges as follows:

PARTIES

1. Plaintiff is a United States citizen residing in Danville, Virginia. (hereafter sometimes, "patient" or "Plaintiff")

2. Defendant, Medical Device Business Services, Inc. is a corporation organized and incorporated in Indiana with its primary place of business in Warsaw, Indiana. This corporation developed, designed, tested, manufactured, distributed and sold the hip implant which is the subject of this lawsuit. (hereafter "DePuy" or " DePuy defendants")

3. Defendant, Johnson & Johnson Services, Inc. is a corporation organized and existing under the law of New Jersey with its primary place of business in New Brunswick, New Jersey. As DePuy's parent company this company was involved in the development, design, testing, manufacturing, distributing and sale of the hip implant which is the subject of this lawsuit. (hereafter "J&J")

4. Defendant, DePuy Synthes Sales, Inc. is a subsidiary, affiliate and/or sister corporation of Johnson & Johnson. Upon information and belief, this company distributed and sold the hip implant which is the subject of this lawsuit. (hereafter "DePuy Sales" or "DePuy defendants")

5. Defendant, CeramTec GmbH, is a company that produces pink-colored ceramic hip implant components sold under the name BIOLOX Delta. This company sells these products to original equipment manufacturers such as, and including, the DePuy and J&J defendants. The DePuy and J&J defendants incorporate BIOLOX Delta products into hip implant systems that DePuy and J&J in turn sells to hospitals and orthopedic surgical groups for use by surgeons in orthopedic surgeries. (hereafter "CeramTec")

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6. Defendant, CeramTec North American Corp. is a subsidiary or affiliate corporation of CeramTec GmbH having a United States presence in Laurens, South Carolina. Upon information and belief, this company distributes and sells CeramTec hip implant products, including the products sold herein, in the United States. (hereafter "CeramTec Sales" or "CeramTec defendants")

7. Defendant, Danville Regional Medical Center, is a subsidiary of LifePoint Health Systems whose primary place of business is Brentwood, Tennessee. This defendant operates the hospital in Danville, Virginia. (hereafter "Hospital")

8. Defendant, Spectrum Medical Inc. is a healthcare provider in the Commonwealth of Virginia whose services include, among other things, orthopedic surgery. (hereafter "Spectrum")

9. Defendant, Matt Wimbish, at all pertinent times, was a manufacturer's representative for the DePuy defendants. At all pertinent times, this defendant resided in Virginia. (hereafter "Wimbish")

JURISDICTION AND VENUE

10. This Court has personal jurisdiction over the DePuy and J&J defendants because they are authorized to do business and in fact do business in this state. These defendants and CeramTec have sufficient minimum contacts with this state and otherwise purposefully avail themselves of the markets in this state through the promotion, marketing, and sale of its hip implant products in Virginia. This Court has Long-arm jurisdiction over CeramTec pursuant to Virginia Code § 8.01-328.1, paragraphs 2, 4, and 5.

11. This Court has subject matter jurisdiction over this action, pursuant to VA. Code §17.1-513.

12. The proper venue for this case lies in Danville inasmuch as the Hospital and Spectrum, have principle places of business located in Danville, Virginia.

FACTS

13. Sometime prior to December 15, 2016, the J&J and DePuy defendants, and the CeramTec defendants, developed, designed, tested, manufactured, distributed, sold, and placed in the stream of commerce a ceramic-on-ceramic total hip replacement prosthesis which is the subject of this lawsuit. Said prosthesis is known as CERMAX Ceramic Total Hip System and is specifically identified by the package "sticker" labeling attached. (Exhibit A). This prosthesis will be hereafter referred to as "the product".

14. On or about December 15, 2016, the defendant Hospital and/or the Spectrum defendant resold the product to the patient, and her surgeon implanted the product in her body during a total hip replacement.

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15. The hip is a ball-and-socket joint, where the ball is the femoral head and the socket is formed by the acetabulum.

16. In a total hip replacement, surgeons remove damaged biological material and implant prosthetic components.

17. In the product which is the subject of this lawsuit, the liner which is part of the acetabulum component, and the femoral head were made of ceramic material by CeramTec.

18. In the product which is the subject of the lawsuit, the ceramic femoral head and liner were manufactured and placed in the stream of commerce by the CeramTec. These component parts were sold to the J&J and DePuy defendants and were used and relied upon in the manufacture and sale of the product.

19. On or about December 15, 2016, the patient underwent a total hip replacement procedure at the Hospital.

20. At the time and place aforesaid, the product was implanted in the patient's body by a surgeon who was an employee and agent of Spectrum, acting within the scope of his employment, authority and agency. (hereafter "surgeon")

21. On or about March 3, 2017 the patient presented to Spectrum reporting "a squeaking pain and increasing pain of her hip". It appeared to Spectrums' orthopedic clinician "that the acetabular liner has displaced completely and is rotated".

22. On or about March 7, 2017, the patient presented again to her original surgeon, at Spectrum, with continued history of increasing hip pain making it even difficult to sleep. Her surgeon concluded that there had been "a fracture of the ceramic liner".

23. After physical examination and x-ray imaging, the surgeon determined that the product had probably malfunctioned and emergent revision surgery was indicated.

24. On or about March 10, 2017, the patient presented to the Hospital for emergent revision surgery.

25. Prior to surgery, the patient specifically told her surgeon that she would like to have the parts that were to be removed from her body, and requested that said explants be given to her. Her surgeon agreed that the product would be preserved and given to the patient.

26. During the revision surgery, the surgeon found that the ceramic liner had indeed "fractured in multiple planes" and that sharp dangerous fragment shards had been deposited in the patient's body.

27. During the revision surgery, the surgeon removed the ceramic head and shattered ceramic liner, and replaced said components with non-ceramic implants.

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28. To the best of the surgeon's ability he removed the shattered ceramic fragments and shards. However, despite his best efforts, all of the dangerous shards could not be removed.

29. At the time of the revision surgery, while the patient was under general anesthesia, the defendant Wimbish took possession of the shattered pieces of the ceramic liner which had been removed from the patient's body. In so doing, defendant Wimbish was acting within the scope of his employment and/or agency with the DePuy defendants, and his actions were in furtherance of DePuy's interests.

30. The patient paid for the product. When it was implanted in her body on or about December 15, 2016, the product thereafter belonged to her.

31. Neither DePuy nor defendant Wimbish had the patient's permission, authorization, or consent to take possession of the product.

32. The ceramic head was retained by the hospital. By report, the head was cracked, but not shattered.

33. Since March 10, 2017, the patient has been hospitalized on several occasions for hip related complications stemming from her original surgery. The patient has undergone a second revision surgery at an outside hospital. Subsequent treating physicians have been unable to remove the remaining dangerous shattered ceramic fragment shards from her body.

34. Upon information and belief, the shattered fragments taken by defendant Wimbish have been examined, inspected, and tested in an attempt to determine the root cause of the failed prosthesis. It is believed, and therefore averred and alleged, that examination, inspection and testing of the failed product took place in Warsaw, Indiana and in Leeds, England. The chain of custody is unknown.

35. On April 7, 2017, lawyers then representing the patient sent a Preservation of Evidence/Spoliation notice letter to the Hospital. (Exhibit B).

36. Upon information and belief, the hospital still has physical possession of the cracked femoral head, which was removed from the patient's body.

37. The hospital has failed and refused to allow the patient to take possession of the femoral head without a "subpoena".

38. On or about April 18, 2017, lawyers then representing the patient sent a Preservation of Evidence/Spoliation notice letter to the DePuy defendants. (Exhibit C).

39. Despite follow-up written requests on July 24, 2017, November 6, 2017 and February 5, 2018, and numerous telephone calls to DePuy, there was no meaningful response

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whatsoever except to identify the attorney who was handling the matter for DePuy until November 23, 2018.

40. Subsequently, despite continuing requests for the results of DePuy's examination, testing, and inspection of the ceramic liner, DePuy has failed and refused to make this information available to the Plaintiff.

41. On or about November 23, 2018, the DePuy defendants belatedly caused to be delivered to the Plaintiff's agent what purported to be the shattered components of the Plaintiff's explanted prosthesis. The fragments and shattered pieces were in an unsecured Ziploc bag with insufficient and confusing identifying information.

42. The DePuy defendants knew that, under these circumstances, at this point in time, it would be virtually impossible for the Plaintiff to determine with reasonable certainty the root cause of her injuries and damage.

43. The product is a Class III medical device which, by definition, is a product having an unreasonable risk of serious bodily injury or death unless approved manufacturing processes are strictly adhered to.

44. During clinical trials, required by the FDA, before marketing the product, the DePuy defendants reported isolated ceramic liner "fracture" to have been observed on x-ray only after more than 18 months of duration of implantation. Subsequent surveillance and reporting of ceramic line "fracture" have provided similar information.

45. Isolated "fracture" is materially different from a ceramic liner "shattering" into many pieces as occurred in the Plaintiff's hip after less than three months of implantation.

46. It is highly unlikely that a ceramic liner would "shatter", as in this case, if the DePuy defendants, during the manufacturing process, had appropriately followed their own protocol as approved by the FDA.

47. The product was in substantially the same condition when implanted in the patient's body as it was when it left the hands of the defendants.

COUNT I
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY BY DEPUY AND J&J DEFENDANTS

48. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

49. At all times relevant to this action, all defendants were merchants with regard to the product at issue.

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50. Said defendants impliedly warranted that the product they either designed, selected, produced, inspected, tested, manufactured, packaged, marketed, distributed, and sold was merchantable under applicable law.

51. Said defendants breached this implied warranty of merchantability because the product was defective, unreasonably dangerous, and neither fit, suitable nor safe for the ordinary purposes for which it was intended, and would not pass without objection in the industry in which it was sold. In this, among other things, in manufacturing the product the DePuy defendants failed to adhere to FDA approved processes and procedures causing a manufacturing defect. Stated differently, the product the patient received was not the product approved by the FDA because defendants did not adhere to FDA manufacturing requirements.

52. As a direct and proximate result of these defendants having breached an implied warranty of merchantability, the patient has suffered injuries and damages described in this Complaint.

COUNT II
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE BY DEPUY AND J&J DEFENDANTS

53. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

54. At all times relevant to this action, these defendants knew or had reason to know that purchasers of the product would be using it in connection with hip replacement, thus relying upon their representation that it was reasonably safe for this particular purpose.

55. Said defendants impliedly warranted that the product they either designed, selected, produced, inspected, tested, manufactured, packaged, marketed, distributed, and sold was fit for the purpose of hip replacement when in fact, it was not.

56. Said defendants breached this implied warranty of fitness for a particular purpose because the product was defective, unreasonably dangerous, and neither fit, suitable nor safe for the particular purpose for which it was manufactured and sold. In this, among other things, in manufacturing the product the DePuy and J&J defendants failed to adhere to FDA approved processes and procedures causing a manufacturing defect. Stated differently, the product the patient received was not the product approved by the FDA because defendants did not adhere to FDA manufacturing requirements.

57. As a direct and proximate result of these defendants' having breached an implied warranty of fitness for a particular purpose, the patient has suffered injuries and damages described in this Complaint.

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COUNT III
BREACH OF IMPLIED WARRANTY MERCHANTABILITY BY CERAMTEC

58. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

59. At all times relevant to this action, all defendants were merchants with regard to the product at issue.

60. Said defendants impliedly warranted that the product they either designed, selected, produced, inspected, tested, manufactured, packaged, marketed, distributed, and sold was merchantable under applicable law.

61. Said defendants breached this implied warranty of merchantability because the product was defective, unreasonably dangerous, and neither fit, suitable nor safe for the ordinary purposes for which it was intended, and would not pass without objection in the industry in which it was sold.

62. As a direct and proximate result of these defendants having breached an implied warranty of merchantability, the patient has suffered injuries and damages described in this Complaint.

COUNT IV
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE BY CERAMTEC

63. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

64. At all times relevant to this action, these defendants knew or had reason to know that purchasers of the product would be using it in connection with hip replacement, thus relying upon their representation that it was reasonably safe for this particular purpose.

65. Said defendants impliedly warranted that the product they either designed, selected, produced, inspected, tested, manufactured, packaged, marketed, distributed, and sold was fit for the purpose of hip replacement when in fact, it was not.

66. Said defendants breached this implied warranty of fitness for a particular purpose because the product was defective, unreasonably dangerous, and neither fit, suitable nor safe for the particular purpose for which it was manufactured and sold.

67. As a direct and proximate result of these defendants' having breached an implied warranty of fitness for a particular purpose, the patient has suffered injuries and damages described in this Complaint.

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Gregory, McGarry
& Wall, P.C.
Martinsville, VA

COUNT V
FAILURE TO WARN BY CERAMTEC

68. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

69. These defendants knew, or had reason to know, that the product would be utilized by orthopedic surgeons and patients in the exact fashion as set forth in this Complaint.

70. These defendants knew, or had reason to know, that without more explicit warnings to surgeons and patients there was an unreasonable risk of breaking, fracture, and shattering of the product. In spite of the unreasonable condition of said product without more explicit warnings, these defendants failed to provide adequate warnings and instructions to patients and surgeons.

71. As a direct and proximate result of these defendants' having failed to warn, the patient has suffered injuries and damages described in this Complaint.

COUNT VI
BREACH OF EXPRESS WARRANTIES BY CERAMTEC

72. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

73. These defendants made certain expressed warranties which falsely minimized the products propensity to break, fracture, and shatter. Among other things, theses defendants misleadingly characterized the product as being comparable to steel in hardness.

74. The patient's surgeon, and indirectly the patient, relied upon this type of expressed warranty to the patient's detriment.

75. These defendants breached their expressed warranties in that the product did not conform to the warranties made by these defendants.

76. As a direct and proximate result of these defendants' having breached the expressed warranty, the patient has suffered injuries and damages described in this Complaint.

COUNT VII
SPOLIATION BY DEPUY AND J&J DEFENDANTS

77. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

78. Ceramics are inherently vulnerable to breakage, fracture, and shattering. Although improvements in materials engineering had greatly reduced fracture rates in ceramic

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Martinsville, VA

femoral heads at the time of the patient's surgery, concerns still existed for ceramic liners at this point in time.

79. Knowing these concerns, commencing with the wrongful conversion of the patient's explanted shattered component, and unauthorized analysis use of the patient's medical records, these defendants embarked on a course of conduct intended and designed to conceal the results of their investigation and testing thereby frustrating, and depriving the patient of her right and opportunity to prove a cause of action for products liability. Stated differently, these defendants have suppressed material evidence most likely favorable to the patient. This wrongful course of action continues to this date. In this, among other things, these defendants have thwarted Plaintiff's right to conduct her own investigation as to the cause of her injury and damage; have failed and refused to share with the patient the results of their root cause investigation and testing; and have made use of the Plaintiff's property and confidential records for their own benefit.

80. These defendants have failed to properly and completely report to the FDA the results of their root cause analysis and testing.

81. Where, as here, these defendants have within their control material evidence and do not disclose it, there is an inference, that the evidence, if it were disclosed, would be unfavorable to the defendants.

82. The defendants knew that evidence which has been suppressed, and continues to be suppressed, is crucial to the Plaintiff's underlying action for products liability.

83. As a direct and proximate result of this wrongful course of action (spoliation), the patient has suffered injuries and damages described in this Complaint.

COUNT VIII
WRONGFUL DISCLOSURE OF MEDICAL INFORMATION BY ALL DEFENDANTS EXCEPT CERAMTEC

84. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

85. At all pertinent times, all persons in control of, in possession of, or exercising dominion over the Plaintiff's explanted components and the Plaintiff's medical records were employees or agents of the Hospital defendant and/or the Spectrum defendant, acting within the scope of their employment, agency, and authority. In this, among other things, no such person was pursuing his own ends, or had external, independent or personal motives; such persons were performing a normal function of their assigned service or task; and, the breach of duty occurred during the very thing the person was being paid to do. Breach of duty occurred while engaged in the very thing the person was being paid to do.

86. DePuy is liable under the doctrine of *respondeat superior* (master servant) for all wrongful acts and omissions of such person. The acts and omission of such persons were intended only to serve the purposes of the Hospital and Spectrum.

87. The Hospital and Spectrum Defendants owed a duty to the Plaintiff not to disclose information gained from the Plaintiff during the course of treatment without the Plaintiff's authorization.

88. These Defendants breached this duty by, among other things (a) allowing the Defendant Wimbish to wrongfully take possession of the explanted component (b) violating HIPAA and also HITECH laws and regulations, and common law duties, in disclosing the Plaintiff's confidential medical information to the DePuy defendants.

89. In breaching this duty of care, these Defendants facilitated, were implicit in, and aided and abetted the wrongful conversion and use of the Plaintiff's property and medical records by the DePuy defendants.

90. As a direct and proximate result of this wrongful course of action (disclosure of medical information), the patient has suffered injuries and damages described in this Complaint.

COUNT IX
WRONGFUL CONVERSION BY ALL DEFENDANTS EXCEPT CERAMTEC

91. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

92. In taking possession of the explanted shattered hardware component, the defendant Wimbish and his employer/principle wrongfully exercised and assumed authority over the Plaintiff's property with intent to deprive the Plaintiff of her right and opportunity to determine the cause of her injuries and damage.

93. Thereafter, despite repeated written and verbal requests, the DePuy and J&J defendants wrongfully failed and refused to provide any meaningful information to the Plaintiff or to heed her requests, from March 10, 2017 until November 23, 2018. These defendants to this day have wrongfully failed and refused to provide the results of the root cause analysis and testing.

94. The DePuy defendants ratified and approved the wrongful conversion of Plaintiff's property by Defendant Wimbish.

95. By wrongfully converting the Plaintiff's property to their own use, the DePuy defendants, in equity, impliedly promised to share with the Plaintiff the results of their examination, inspection, and testing.

96. The DePuy defendants, having assumed possession of the fractured explants (along with the Plaintiff's confidential medical records) were under a duty to investigate and

determine the root cause of the product failure and to report their findings to the Food & Drug Administration (FDA) and to the Plaintiff.

97. In addition to the wrongful conversion of the Plaintiff's explanted failed hip component the DePuy Defendants wrongfully acquired the Plaintiff's personal health information (confidential medical records) without the Plaintiff's authorization, permission, or consent.

98. The Hospital and Spectrum Defendants were complicit in, facilitated, and aided and abetted wrongful conversion of the fractured implant. In this, among other things, these defendants allowed the Defendant Wimbish to take possession of the failed explanted component, and leave the premises; and these Defendants, without authorization, delivered to the DePuy Defendants, or allowed DePuy Defendants to take possession of Plaintiff's confidential medical records.

99. As a direct and proximate result of this wrongful course of action (conversion), the patient has suffered injuries and damages described in this Complaint.

COMPENSATORY DAMAGES AS TO ALL DEFENDANTS

100. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

101. As a direct and proximate result of the acts and omissions of the DePuy and J&J defendants, and the CeramTec defendants, as set forth in Counts I, II, III, IV, V, and VI, the Plaintiff has been required to incur medical and related expense in the past, and will require even further such expenses in the future; has suffered in the past, and continues to suffer, and will suffer in the future severe emotional and mental anguish and distress with physical inconvenience and other physical ramifications, all attributable to the aforesaid acts and omissions, breaches of warranties and other actions described in Counts I through VI; the Plaintiff suffered specific direct injury to her person; was caused other serious and permanent injuries about her person internally and externally; was caused excruciating pain and mental anguish; was maimed and disabled; and, was rendered less capable of performing her normal daily tasks all due to her damage.

102. As a direct and proximate result of the spoliation, wrongful disclosure of medical information, and wrongful conversion by all defendants except CeramTec, as set forth in Counts VII, VIII, and IX, the Plaintiff has lost a fair and timely opportunity to prove her underlying products liability claim; has been deprived of her property; and has suffered an invasion of her privacy; and has been otherwise thwarted and frustrated in her attempts to prove the cause of her injury and damage, all of which has caused the Plaintiff great mental anguish and distress.

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PUNITIVE DAMAGES AS TO DEPUY AND J&J DEFENDANTS

103. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

104. The aforesaid acts and omissions attributable to the DePuy and J&J defendants, as set forth in Counts VII, VIII, and IX, constitute willful and wanton conduct; that is, acting consciously in disregard of civil obligations and the Plaintiff's rights, or acting with reckless indifference to the consequences. These defendants conduct and course of action was so willful and wanton that it shows a conscious disregard of the rights of others. There are severe criminal and civil penalties for HIPAA violations. The tort of conversion, as in this case, is tantamount to grand larceny.

WHEREFORE, Plaintiff moves the Court for judgment against the Defendants jointly and severally for compensatory damages in the amount of $2,500,000.00 (Two million five hundred thousand dollars) prejudgment and other interest as may be appropriate, and her cost in this behalf expended; Plaintiff further moves the Court for punitive damages in the amount of $350,000.00 (Three hundred fifty thousand dollars).

A TRIAL BY JURY IS REQUESTED.

Respectfully submitted,

SUSAN O. CARDOZA

By: _____
Of Counsel

Robert W. Mann, Esquire (VSB #07622)
YOUNG, HASKINS, MANN, GREGORY, MCGARRY & WALL, P.C.
Post Office Box 72
Martinsville, VA 24114-0072
Telephone (276)-638-2367
Facsimile (276)-638-1214
Email: RWMann@comcast.net

DO NOT USE ABBREVIATIONS:

I, QD, QOD, trailing zero (1.0mg), µg, lack of leading zero (.1 mg), MS, MSO4, MgSO4

TIME	
1000	Right total hip

REF 1246-03-000 LOT D16081836
APEX™
HOLE ELIMINATOR - PS
(01)10603295019688
(17)260731(10)D16081836
2026-07-31
STERILE R
QTY 1
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw IN 46582
1-800-366-4143
REV. F

REF 1217-31-052 LOT C91788
PINNACLE® 100
ACETABULAR SHELL 100
52mm OD GRIPTION™
(01)10603295010203
(17)260930(10)C91788
STERILE R 2026-09-30
QTY 1
REV. D

REF 1218-87-652 LOT 8388193
CERAMAX™
Ceramic Insert
NEUTRAL 52mm OD 38mm ID
(01)10603295012611
(17)210831(10)8388193
STERILE R 2021-08-31
QTY 1
REV. C

REF 1365-36-310 LOT 8398876
BIOLOX® DELTA
CERAMIC FEMORAL HEAD
+1.5 36mm DIA 12/14 TAPER
(01)10603295033615
(17)210930(10)8398876
STERILE R 2021-09-30
QTY 1
REV. E

REF 3L92510 LOT 5259977
CORAIL® HIP SYSTEM
CEMENTLESS FEMORAL STEM
HA COATED 12/14 AMT 135°
STANDARD NO COLLAR KS SIZE 10
(01)10603295169769
(17)201031(10)5259977
STERILE R 2020-10-31
QTY 1
REV. H

FILED
2018 DEC 13 PM 12:00
CLERKS OFFICE
CIRCUIT COURT
DANVILLE VIRGINIA

PLAINTIFF'S EXHIBIT
A.

USE BLACK INK ONLY

Patient Information/Label

CARDOZA, SUSAN MARIE

Physician's Progress Report

PROGRESS RECORD

DO NOT USE ABBREVIATIONS:

IU, QD, QOD, trailing zero (1.0mg), µg, lack of leading zero (.1 mg), MS, MSO4, MgSO4

	TIME	
7	955	REF 1221-38-482 LOT C20480 STERILE GP 2021-03-31 PINNACLE ALTRX POLYETHYLENE ACETABULAR LINER +4 NEUTRAL 36mm ID 52mm OD (01)10603295016489 (17)210331(10)C20480 QTY 1 REV. E — Right hip
		REF 1365-51-000 LOT 8391060 STERILE R 2021-09-30 M-SPEC™ METAL FEMORAL HEAD Ø36mm +1.5 12/14 TAPER (01)10603295033912 (17)210930(10)8391060 QTY 1 REV. E
7	9:30	[illegible]
		[illegible]
		[illegible] Hb 9.5
		[illegible]
		[illegible]

0 -473-3789

[illegible signature]

USE BLACK INK ONLY

LUIS A. ABREU, PLLC

ATTORNEYS AT LAW

Luis A. Abreu
labreu@luisabreulaw.com

Michael D. Simmons
msimmons@luisabreulaw.com

P. O. Box 1598
626 North Ridge Street
Danville, Virginia 24543
www.luisabreulaw.com

(434) 791-4677
Fax: (434) 791-4676

April 7, 2017

VIA U.S. Mail and Certified Mail, Return Receipt Requested

Danville Regional Medical Center
142 South Main Street
Danville, VA 24541

FILED
2018 DEC 13 PM 12:00
CLERK'S OFFICE
CIRCUIT COURT
DANVILLE, VIRGINIA

Preservation of Evidence/ Spoliation Notice

RE: Our Client: Susan Olival Cardoza
Address: 172 Graymont Place
Danville, VA 24541
Date of Birth: 12/19/1953
Social Security #: ###-##-0687

Dear Sir/Madam:

Please be advised that we represent Susan Cardoza with respect to her injuries sustained from a failed hip replacement performed on December 15, 2016. Please provide us with a complete copy of your file regarding services rendered to Ms. Cardoza including, but not limited to, office notes, radiology reports, diagnostic reports, disability slips, prescriptions, statement of account with CPT and ICD-9 codes, etc. Please also provide us with copies of all documentation relating to the hip replacement and parts used in the hip replacement surgery. Enclosed is an original of Danville Regional Medical Hospital's Authorization For Release Of Protected Health Information which has been signed by Ms. Cardoza.

This letter is to also put Danville Reginal Medical Hospital on notice that it must preserve all data of any type relating to the claim. Most importantly, all of the hip replacement parts removed during the operation must be preserved. This includes the CERAMAX Ceramic Insert, BIOLOX Delta Ceramic Femoral Head, and any other part that was replaced on March 10, 2017. Please ensure this letter is provided to the appropriate person in your office who is charged with the custody of the above items.

Please do not dispose of any of this material, as I expect that it will be both discoverable and admissible in any litigation that may arise out of this claim. Failure to preserve this material will result in a request for a spoliation instruction at any trial in this matter.

If you are no longer in possession of these parts, please identify who has or took these parts (and their contact information). Please also share the circumstances under which the parts were removed during the second surgery.

LUIS A. ABREU
ATTORNEY AT LAW

Thank you for your assistance in this matter. If you have any questions, please do not hesitate to call us at 434-791-4677 during regular business hours.

Very truly yours,

Michael D. Simmons

MDS/lrp

Enclosure

cc: Ms. Susan Olival Cardoza (W/O Enclosure)
(VIA Electronic Transmission and U.S. Mail)

Mark C. Hermann, M.D. (W/O Enclosure)
(VIA U.S. Mail)

LUIS A. ABREU, PLLC

ATTORNEYS AT LAW

Luis A. Abreu
labreu@luisabreulaw.com

Michael D. Simmons
msimmons@luisabreulaw.com

P. O. Box 1598
626 North Ridge Street
Danville, Virginia 24543
www.luisabreulaw.com

(434) 791-4677
Fax: (434) 791-4676

April 18, 2017

VIA Certified Mail, Return Receipt Requested, and Electronic Transmission

DePuy Synthes Joint Reconstruction
700 Orthopaedic Drive
Warsaw, IN 46582

Preservation of Evidence/ Spoliation Notice

RE: Our Client: Susan Olival Cardoza
Address: 172 Graymont Place
Danville, VA 24541
Date of Birth: 12/19/1953
Social Security #: ###-##-0687

Dear Sir/Madam:

Please be advised that we represent Susan Cardoza with respect to her injuries sustained from a failed hip replacement performed on December 15, 2016. It is requested that you provide us with a complete copy of your file regarding services or products rendered to Ms. Cardoza. Please also provide us with copies of all documentation relating to the hip replacement and parts used in the hip replacement surgery.

This letter is to also put DePuy Synthes on notice that it must preserve all data of any type relating to the claim. Most importantly, all of the hip replacement parts removed during the operation must be preserved. This includes, without limitation, the CERAMAX Ceramic Insert, BIOLOX Delta Ceramic Femoral Head, and any other part that was replaced on March 10, 2017. We have attempted to contact your employee, Richard Fox with Quality Control, whose name was given to us by the office of the treating physician, Dr. Mark C. Hermann. We were notified by Dr. Hermann's office that Mr. Fox had the pieces described above. We were advised that the Case Number is COM-271-588 and the phone number provided to us for Mr. Fox is 1-866-811-9367. We have left several messages at that phone number but have not received any response or call backs, and we are attempting to notify Mr. Fox and DePuy that any and all parts of the hip replacement removed from Ms. Cardoza's hip after the surgery are to be preserved. Please ensure this letter is provided to the appropriate person in your office who is charged with the custody of the above items.

Please do not dispose of any of this material, as I expect that it will be both discoverable and admissible in any litigation that may arise out of this claim. Failure to preserve this material will result in a request for a spoliation instruction at any trial in this matter.

LUIS A. ABREU
ATTORNEY AT LAW

If you are no longer in possession of these parts, please identify who has or took these parts (and their contact information). Please also share the circumstances under which the parts were removed during the second surgery.

Thank you for your assistance in this matter. If you have any questions, please do not hesitate to call us at 434-791-4677 during regular business hours.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan Olival Cardoza (VIA Electronic Transmission and U.S. Mail)

Mark C. Hermann, M.D. (VIA U.S. Mail)

VIRGINIA: IN THE CIRCUIT COURT FOR THE CITY OF DANVILLE

Susan O. Cardoza,

Plaintiff,

v.

Medical Device Business Services, Inc.
(Formally DePuy Orthopedics Inc.)
700 Orthopaedic Drive
Warsaw, IN 46581

and

Johnson & Johnson Services, Inc.
(Johnson & Johnson)
One Johnson & Johnson PLZ
New Brunswick, NJ 08933

and

DePuy Synthes Sales, Inc.
325 Paramount Drive
Raynham, MA 02767

and

CeramTec GmbH
CeramTec – Platz 1-9
73207, Plochingen
Germany

and

CeramTec North American Corp.
CeramTec Subsidiary, American Headquarters
One Technology Place
Laurens, SC 29360

and

Danville Regional Medical Center, LLC
(d/b/a SOVAH Danville)
103 Powell Ct., Ste 200
Brentwood, TN 37027

FIRST INTERROGATORIES, REQUESTS FOR PRODUCTION OF DOCUMENTS, AND REQUESTS FOR ADMISSIONS TO DEPUY DEFENDANTS
Case No. CL18000850-00

Law Offices
Young, Haskins, Mann,
Gregory, McGarry
& Wall, P.C.
Martinsville, VA

and

Spectrum Medical Inc.
109 Bridge Street, Suite 300
Danville, VA 24541

and

Matt Wimbish
Roanoke, Virginia

Defendants

PLAINTIFF'S FIRST SET OF INTERROGATORIES, REQUESTS FOR PRODUCTIONOF DOCUMENTS AND REQUESTS FOR ADMISSIONS TO MEDICAL DEVICE BUSINESS SERVICES, INC., JOHNSON & JOHNSON SERVICES, INC., AND DEPUY SYNTHES SALES, INC.

NOW COMES Plaintiff, Susan O. Cardoza, by counsel, pursuant to Rules 4:8, 4:9 and 4:11 of the Rules of the Supreme Court of Virginia, and propounds the following discovery to the captioned Defendants: Medical Device Business Services, Inc., Johnson & Johnson Services, Inc. and DePuy Synthes Sales, Inc.

DEFINITIONS

To facilitate your answers to this discovery, the terms used herein have the following meanings unless the context requires otherwise.

1. "The product" refers to CERAMAX Ceramic Total Hip System. (containing Biolox Delta), more specifically described and identified in the product labeling or product "stickers" attached as Exhibit A to the Complaint filed herein.
2. The "incident in question" refers to the failure of Ms. Cardoza's prosthetic hip which was implanted in her body December 15, 2016.
3. "Explanted liner components" refers to the fractured ceramic liner pieces removed from Ms. Cardoza's body at the time of revision surgery, March 10, 2017. "Explanted head"

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refers to the ceramic head removed from Ms. Cardoza's body at the time of revision surgery, March 10, 2017.

4. "You" or "your" or "DePuy" refers to Medical Device Business Services Inc. (Formally DePuy Orthopedics Inc.), Johnson & Johnson Services Inc., and DePuy Synthes Sales Inc., its successors, predecessors, agents and employees and all other persons acting on behalf of said defendants.

5. "Documents"' or "writings of every kind and description" means all written, typed or printed matter and all magnetic or other records or documentation of any kind or description (including, without limitations, letters, correspondence, telegrams, memoranda, notes, records, minutes, contracts, agreements, records or notations of telephone or personal conversations, conferences, interoffice communications, microfilm, bulletins, circulars, pamphlets, photographs, artists' renderings, invoices, tape recordings, computer printouts and work sheets), including, drafts and copies not identical to the originals, all photographs and graphic matter, however produced or reproduced, and all compilations of data from which information can be obtained, and any and all writings or recordings of any type or nature in your actual or constructive possession, custody or control, including those in the possession, custody or control of any and all present or former directors, officers, employees, consultants, accountants, attorneys or other agents, whether or not prepared by you.

6. "Report" means the results of any examination, inspection, testing, or audits performed by the DePuy defendants, or at the direction and request of DePuy defendants by others.

7. The words "describe" or "identify" when referring to a person are meant to request that you set forth the following information: (a) Full name. (b) Present or last known residential address. (c) Present or last known telephone number. (d) Present occupation, job title, employer and employer's address. (e) Occupation, job title, employer and

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employer's address at the time of the event or period referred to in each particular Interrogatory. (f) In the case of any person other than an individual, identification of the officer, employee or agent most closely connected with the subject matter of that Interrogatory and of the officer who is responsible for supervising that officer or employee with regard to the subject matter of that Interrogatory.

8. The words "describe" or "identify" when referring to a document, are meant to request that you set forth the following information: (a) The nature (*e.g.*, letter, handwritten note) of the document. (b) The title or heading that appears on the document. (c) The date of the document and the date of each addendum, supplement or other addition or change. (d) Identification of the author and of the signor thereof, and of the person on whose behalf or at whose request or direction the document was prepared or delivered. (e) Identification of the addressee or recipient thereof, if any. (f) The present location of the document, and the name, address, position or title and telephone number of the person or persons having custody.

INTERROGATORIES

1. Identify the person(s) signing and verifying your answers to this discovery. Identify all persons who were contacted in order to answer to this discovery. Identify DePuy's most knowledgeable person regarding the investigation into your complaint file COM-27-588 and the incident in question. Indentify DePuy's most knowledgeable person regarding the chain of custody for the explanted liner component.

ANSWER:

2. Identify all persons involved in the chain of custody pertaining to the Plaintiff's explanted liner components; and, describe any and all precautions used to assure the safety, security and integrity of the explanted liner components. This question is

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Martinsville, VA

intended for you to disclose, in detail, all circumstances regarding possession and handling of the explanted liner components from the time said components left the surgical tray at the Danville hospital on March 10, 2017 until the time said components were sent to 400 Starling Avenue, Martinsville, Virginia by FedEx on November 21, 2018. Include any and all accidental breakage or damage to the explanted liner components after said components came into the possession of Mr. Wimbish.

ANSWER:

3. How many pieces were there of the explanted liner components when Mr. Wimbish took possession of said components at the Danville hospital. How many pieces of the explanted liner components were placed in the FedEx shipment sent to 400 Starling Avenue, Martinsville, Virginia on November 21, 2018? Indentify and describe all documents and writings of every kind and description in support of your answer.

ANSWER:

4. Indentify and describe, with particularity, all examination, inspections, and testing of the explanted liner components including, but not limited to, all testing to determine hardness, elasticity, and propensity to fracture or break.

ANSWER:

5. Indentify and describe, with particularity, all inspection, examination, and testing of the explanted liner components which was specifically done in an effort to determine the root cause of fracture of the explanted liner component in Ms. Cardoza's hip.

ANSWER:

6. Indentify and describe, with particularity, all inspection, examination, testing, and analysis specifically done to determine whether the explanted liner component was manufactured in compliance with the FDA approved protocol for this product.

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ANSWER:

7. Indentify and describe, with particularity, any destructive testing done on the explanted liner component. Include, but do not limit your answer to, any and all chemical analysis for inclusions; any and all chemicals used to sanitize the explanted liner component; and all other chemical or physical alterations of the explanted liner components. How did you assure that there was no deleterious effect as a result of your procedures and analysis?

ANSWER:

8. What is the last known address of Matthew (Matt) Wimbish? Indentify and describe his employment or agency responsibilities with DePuy.

ANSWER:

9. Indentify and describe, with particularity, when, where, and under what circumstances Mr. Wimbish originally took possession of the fractured explanted liner components.

ANSWER:

10. Indentify and describe, with particularity, all witnesses to Mr. Wimbish having assumed possession of the explanted liner components. Indentify all documents, or paper trail pertaining to this acquisition including, but not limited to, Mr. Wimbish's notes and/or reports.

ANSWER:

11. Indentify and describe, with particularity, when, where, and under what circumstances you acquired Ms. Cardoza's medical records. Indentify all witnesses to this acquisition. Indentify all documents, or paper trail pertaining to this acquisition.

ANSWER:

12. Indentify and describe, with particularity, the root cause of Ms. Cardoza's ceramic

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liner failure and the underlying reasons and contributing causes for such failure. Indentify any documents wherever you referred to attempts to determine the root cause.

ANSWER:

13. State whether or not, as a result of the incident in question, there was any corrective action, recommendations or suggestions with regard to manufacture, sale, and/or repossession of ceramic liner components. If so, identify and explain.

ANSWER:

14. If you contend that Ms. Cardoza, or any third party, caused or significantly contributed to the fracture and failure of the ceramic liner, identify the individual and company and set forth the complete basis for your contention.

ANSWER:

15. Prior to receiving notification of representation from undersigned counsel, sent October 10, 2018 (See Exhibit A), state whether or not your file and investigation of Ms. Cardoza's explanted liner component and the incident in question had been completed and closed. If not, what remained to be done? Explain why there had been no previous response to the repeated requests made by Mr. Simmons. (See Exhibit A)

ANSWER:

16. Indentify and describe, with particularity, your quality assurance protocol to assure compliance with FDA PMA approval. Include, but do not limit your answer to, process controls on raw materials or other materials received from CeramTec or others. Include, but do not limit your answer to, protocols with respect to insuring proper hardness, appropriate elasticity, and minimizing propensity for breakage and fracture.

ANSWER:

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17. In connection with your examination, inspection, and testing of the explanted liner components, was any failure analysis performed? If so, what was specifically done and what were the conclusions? For example: (a) Were the components analyzed to assure its composition and microstructure complied with design specifications? If so, explain. (b) Were the liner components assessed in any way to assure compliance with design specifications for strength, toughness, hardness, wear resistance, and propensity to breakage or fracture? If so, explain. (c) Were the fracture surfaces of the explanted liner components examined to determine if the material had defects that could act as stress raisers? If so, explain.

ANSWER:

18. Indentify and describe, all internal and external audits pertaining to the relevant lots from which Ms. Cardoza's prosthesis was produced.

ANSWER:

19. Indentify and describe, all complaints known to you pertaining to the CERAMAX Ceramic Total Hip System (containing Biolox Delta) from 2000 to the present. Include, but do not limit your description to, whether or not the complaints related to fracture of the ceramic liner.

ANSWER:

20. Indentify and describe, by date, jurisdiction, court, and attorneys and deposition all lawsuits against you from the year 2000 to the present pertaining to alleged defects in the CERAMAX Ceramic Total Hip System (containing Biolox Delta).

ANSWER:

21. If your response to any of the following request for admissions is anything other than an unqualified admission, state in detail and explain the basis for your response and identify all witnesses and documentation which justify your refusal to admit.

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Martinsville, VA

ANSWER:

Requests For Production Of Documents

1. Produce DePuy's file pertaining to case COM-27-588, omitting nothing.

RESPONSE:

2. Produce all documents and correspondence, of every kind and description, pertaining to the incident in question. Include, but do not limit your answer to, all correspondence to and from:

a. Other defendants in this lawsuit

b. FDA

c. Internal correspondence

d. Outside consultants

RESPONSE:

3. Produce all reports, memorandums, results, or analysis pertaining to all testing, examination, and inspection of Ms. Cardoza's explanted liner components.

RESPONSE:

4. Produce all findings and non-compliance reports from internal and external audits regarding the lots involved in interrogatory 18.

RESPONSE:

5. Produce your file (personnel file or the like) for Matthew (Matt) Wimbish.

RESPONSE:

6. Produce all writings, of every kind and description, authored or made by Mr. Wimbish in connection with the incident in question.

RESPONSE:

7. Produce all writings, of every kind and description, sent to Mr. Wimbish by employees or agents of any of the DePuy or J&J defendants in connection with the incident in question.

RESPONSE:

8. Produce any notice letters, correspondence, or writings, of every kind and description, to and from any of the DePuy/J&J defendants and to and from the CeramTec defendants.

RESPONSE:

9. Produce all micrographs, and imaging, of every kind and description, done in connection with investigation, examination and testing of the explanted liner components. Include all indentifying data pertaining to the imaging produced.

RESPONSE:

10. Produce all of your policies, protocols, or procedures pertaining to repossession or taking possession of explanted prosthesis after revision surgery.

RESPONSE:

11. Produce all policies, procedures, or protocols concerning compliance with FDA approved requirements for the products.

REPONSE:

12. Produce a Privilege Log pursuant to Virginia Code § 4:1 (a) (6) (i) indentifying any information, or requested information, in this discovery for which you claim privilege.

RESPONSE:

13. Produce all documentation in support of your conclusion or assertion in Exhibit A (Hahn letter) that Ms. Cardoza's implanted hip was not defective in any way.

RESPONSE:

14. Produce all documents and correspondence, of every kind and description, concerning or pertaining in any way to your attempts to acquire, and acquiring, Ms. Cardoza's medical records.

RESPONSE:

15. Produce all documents and correspondence, of every kind and description, concerning or pertaining in any way to your attempts to acquire, and acquiring, Ms. Cardoza's explanted head.

RESPONSE:

16. Produce all documents and correspondence, of every kind and description, concerning or pertaining in any way to your attempts to acquire, and acquiring, Ms. Cardoza's explanted liner components.

RESPONSE:

17. Produce all documents, related to or in any way concerning the chain of custody of the explanted liner components.

RESPONSE:

18. Produce all documents indentified in answers to the preceding interrogatories and/or consulted, used, and/or relied upon in preparing answers to this discovery.

RESPONSE:

Requests For Admissions

1. Admit the authenticity and genuineness of correspondence in Exhibit A between agents for DePuy and agents for Ms. Cardoza.

RESPONSE:

2. Admit that, prior to and on the date of the incident in question, it was the custom and practice of DePuy to take possession if possible, or at least seek possession, of all failed implants after revision surgery.

REPSONSE:

3. Admit that, in the past, in keeping with the aforesaid practice DePuy has compensated surgeons financially for acquiring the patient's consent and authorization to release explanted components to DePuy.

RESPONSE:

4. Admit that your acquisition, possession of, and testing of the explanted components was I the ordinary course of business.

REPSONSE:

5. Admit that your acquisition, possession of, and analysis of Ms. Cardoza's medical records was in the ordinary course of business.

REPONSE:

6. Admit that your creation and maintenance of Complaint File COM-27-588 was in the ordinary course of business.

RESPONSE:

7. Admit that, neither DePuy, nor Mr. Wimbish, had Ms. Cardoza's permission, consent, or authorization for you to take possession of her explanted component(s).

RESPONSE:

8. Admit that, when Mr. Wimbish took possession of Ms. Cardoza's explanted component(s), he was acting in furtherance of DePuy's ends, and had no independent personal motive of his own.

REPSONSE:

Law Offices
Young, Haskins, Mann,
Gregory, McGarry
& Wall, P.C.
Martinsville, VA

9. Admit that, in connection with the incident in question, Mr. Wimbish was DePuy's agent and acting within the scope of his authority and agency.

REPSONSE:

10. Admit that, at all pertinent times, you knew that you did not have Ms. Cardoza's authorization, permission, or consent to possess and exercise dominion over her explanted hip component.

RESPONSE:

11. Admit that, at all pertinent times, you knew that it was improper and unlawful to possess and exercise dominion over Ms. Cardoza's explanted hip without her authorization, permission, and consent.

RESPONSE:

12. Admit that, at all pertinent times, you knew that you did not have Ms. Cardoza's authorization, permission, or consent to possess and exercise dominion over her medical records.

RESPONSE:

13. Admit that, it is unlikely that Ms. Cardoza's ceramic hip implant would have fractured, in separate pieces, in less than three months of implantation, as in this case, if FDA approved protocols and requirements had been followed.

RESPONSE:

14. Admit that, at all pertinent times, you knew that it was improper and unlawful to possess and exercise dominion over Ms. Cardoza's medical records without her authorization, permission, and consent.

RESPONSE:

Respectfully submitted,

SUSAN O. CARDOZA

By: _____
Of Counsel

Robert W. Mann, Esquire (VSB #07622)
YOUNG, HASKINS, MANN, GREGORY, MCGARRY & WALL, P.C.
Post Office Box 72
Martinsville, VA 24114-0072
Telephone (276)-638-2367
Facsimile (276)-638-1214
Email: RWMann@comcast.net

CERTIFICATE OF SERVICE

I certify that a true and exact copy of the foregoing Plaintiff's First Set of Interrogatories, Requests for Production of Documents and Requests for Admissions was sent by first class mail, postage fully pre-paid, to William A. Hahn, II, Esquire, 11 South Meridian Street, Indianapolis, IN 46204-3535, attorney for DePuy and J&J defendants; Ashley Calkins, Esquire, P.O. Box 72050, Richmond, Virginia 23255-2050 attorney for Danville Regional Medical Center LLC; Spectrum Medical Inc., 109 Bridge St., Suite 300, Danville, Virginia, 24541 and CeramTec GmbH, CeramTec-Platz 1-9, 73207, Plochingen, Germany, on this 19th day of December 2018 to:

_____
Robert W. Mann

EXHIBIT A INDEX

Description	Bates#
Preservation Letter to DePuy (04/18/2017)	001
Letter to Mr. Hahn (07/24/2017)	002
Letter to Mr. Hahn (11/06/2017)	003
Letter to Mr. Hahn (02/05/2018)	004
Letter to Mr. Hahn (10/10/2018)	005
Mr. Hahn letter to Mr. Mann (11/14/2018)	006
Email to Mr. Hahn from Mr. Mann (11/19/2018)	007

LUIS A. ABREU, PLLC

ATTORNEYS AT LAW

Luis A. Abreu
labreu@luisabreulaw.com

Michael D. Simmons
msimmons@luisabreulaw.com

P. O. Box 1598
626 North Ridge Street
Danville, Virginia 24543
www.luisabreulaw.com

(434) 791-4677
Fax: (434) 791-4676

April 18, 2017

VIA Certified Mail, Return Receipt Requested, and Electronic Transmission

DePuy Synthes Joint Reconstruction
700 Orthopaedic Drive
Warsaw, IN 46582

Preservation of Evidence/ Spoliation Notice

RE: Our Client: Susan Olival Cardoza
Address: 172 Graymont Place
Danville, VA 24541
Date of Birth: 12/19/1953
Social Security #: ###-##-0687

Dear Sir/Madam:

Please be advised that we represent Susan Cardoza with respect to her injuries sustained from a failed hip replacement performed on December 15, 2016. It is requested that you provide us with a complete copy of your file regarding services or products rendered to Ms. Cardoza. Please also provide us with copies of all documentation relating to the hip replacement and parts used in the hip replacement surgery.

This letter is to also put DePuy Synthes on notice that it must preserve all data of any type relating to the claim. Most importantly, all of the hip replacement parts removed during the operation must be preserved. This includes, without limitation, the CERAMAX Ceramic Insert, BIOLOX Delta Ceramic Femoral Head, and any other part that was replaced on March 10, 2017. We have attempted to contact your employee, Richard Fox with Quality Control, whose name was given to us by the office of the treating physician, Dr. Mark C. Hermann. We were notified by Dr. Hermann's office that Mr. Fox had the pieces described above. We were advised that the Case Number is COM-271-588 and the phone number provided to us for Mr. Fox is 1-866-811-9367. We have left several messages at that phone number but have not received any response or call backs, and we are attempting to notify Mr. Fox and DePuy that any and all parts of the hip replacement removed from Ms. Cardoza's hip after the surgery are to be preserved. Please ensure this letter is provided to the appropriate person in your office who is charged with the custody of the above items.

Please do not dispose of any of this material, as I expect that it will be both discoverable and admissible in any litigation that may arise out of this claim. Failure to preserve this material will result in a request for a spoliation instruction at any trial in this matter.

LUIS A. ABREU
ATTORNEY AT LAW

If you are no longer in possession of these parts, please identify who has or took these parts (and their contact information). Please also share the circumstances under which the parts were removed during the second surgery.

Thank you for your assistance in this matter. If you have any questions, please do not hesitate to call us at 434-791-4677 during regular business hours.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan Olival Cardoza (VIA Electronic Transmission and U.S. Mail)

Mark C. Hermann, M.D. (VIA U.S. Mail)

LUIS A. ABREU, PLLC

ATTORNEYS AT LAW

Luis A. Abreu
labreu@luisabreulaw.com

Michael D. Simmons
msimmons@luisabreulaw.com

P. O. Box 1598
626 North Ridge Street
Danville, Virginia 24543
www.luisabreulaw.com

(434) 791-4677
Fax: (434) 791-4676

July 24, 2017

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

William A. Hahn, II, Esq.
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204-3535

RE: Our Client: Susan Olival Cardoza

Dear Mr. Hahn:

As you may recall, our firm contacted you about Ms. Susan Cardoza's hip replacement parts that were taken by a DePuy representative and subsequently shipped to the U.K. We have not heard from you since May 5, 2017. We are requesting an update on those parts and any relevant information you may have. It is our belief that any testing by DePuy should have been completed by this time and progress in the analysis of the parts should be well under way.

Please update us as soon as possible. We look forward to hearing from you. If you have any questions, please call us at 434-791-4677.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan O. Cardoza (VIA Electronic Transmission and U.S. Mail)

002

LUIS A. ABREU, PLLC

ATTORNEYS AT LAW

Luis A. Abreu
labreu@luisabreulaw.com

Michael D. Simmons
msimmons@luisabreulaw.com

P. O. Box 1598
626 North Ridge Street
Danville, Virginia 24543
www.luisabreulaw.com

(434) 791-4677
Fax: (434) 791-4676

November 6, 2017

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

William A. Hahn, II, Esq.
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204-3535

RE: Our Client: Susan Olival Cardoza

Dear Mr. Hahn:

As you may recall, our firm represents Ms. Susan Cardoza in connection with the injuries she sustained when her total hip replacement surgery in December of 2016 failed. We have not heard from you since May 5, 2017, regarding the removed parts that were sent to the United Kingdom for testing, although we have requested an update on multiple occasions. Please update us as soon as possible, since we need to move forward. In addition, we are requesting that the removed parts be made available to us, or a representative on our behalf, so that we may make an independent evaluation of those parts. Furthermore, we remind you that all the parts need to be preserved as evidence.

Please update us as soon as possible. We look forward to hearing from you. If you have any questions, please call us at 434-791-4677.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan O. Cardoza (VIA Electronic Transmission and U.S. Mail)

LUIS A. ABREU, PLLC
ATTORNEYS AT LAW

Luis A. Abreu
labreu@luisabreulaw.com

Michael D. Simmons
msimmons@luisabreulaw.com

P. O. Box 1598
626 North Ridge Street
Danville, Virginia 24543
www.luisabreulaw.com

(434) 791-4677
Fax: (434) 791-4676

February 5, 2018

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

William A. Hahn, II, Esq.
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204-3535

RE: Our Client: Susan Olival Cardoza

Dear Mr. Hahn:

As you may recall, we represent Ms. Susan Cardoza in the injuries she sustained when her total hip replacement failed. The purpose of this letter is to give you the opportunity to share with us the reason(s) for the failure of the hip replacement parts. Ms. Cardoza's medical records do not expound upon the reason(s) for the failure, and if you are aware of whether it was a manufacturing defect(s), an incorrect installation, or other error, we hope that you would share with us your position as to any reasons her first two operations were not successful.

Finally, we remind you that all the evidence in this matter must be preserved.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan Olival Cardoza
(VIA Electronic Transmission and U.S. Mail)

004

LAW OFFICES

YOUNG, HASKINS, MANN, GREGORY, McGARRY & WALL

A PROFESSIONAL CORPORATION

JAMES W. HASKINS
ROBERT W. MANN*
JOHN L. GREGORY, III
JAMES R. McGARRY
SCOTT C. WALL

400 STARLING AVENUE
POST OFFICE BOX 72
MARTINSVILLE, VIRGINIA 24114-0072
RWMANN@COMCAST.NET

R.R. (JIM) YOUNG, JR.
(1922-1995)

PHONE (276) 638-2367
FAX (276) 638-1214

October 10, 2018

Certified Mail Return Receipt Letter
William A. Hahn II, Esquire
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204

RE: *DePuy case number: COM-271-588*
*Susan Cardoza, DOB: 12/19/1953, SSN: ***-**-0687*

Dear Mr. Hahn:

We are associated with Luis A. Abreu and Michael D. Simmons representing Ms. Cardoza. We have been retained to file suit in this matter. I am enclosing an updated HIPPA authorization and request.

I am also enclosing the initial notice letter and request dated April 18, 2017, along with self-explanatory correspondence dated July 24, 2017, November 6, 2017, and February 5, 2018. It is my understanding there has been no response.

It is apparent that DePuy took possession of the failed implant on the date of Ms. Cardoza's revision surgery, March 10, 2017. It is our understanding that DePuy subsequently conducted an investigation and appropriate testing to determine the root cause of failure. We assume that an appropriate Medical Device Report was filed with the FDA as required by law. In addition to the information previously requested, this request is for all communications relative to this matter between DePuy and the FDA.

Time is of extreme essence. The applicable statute of limitations requires that appropriate action must be filed on or before December 15, 2018. Accordingly, please let me hear from you at your very first convenience.

Very truly yours,

Robert W. Mann

RWM/hmb
Enclosures
Cc: Michael D. Simmons, Esquire
Luis Abreu, Esquire

*CERTIFIED SPECIALIST IN CIVIL TRIAL ADVOCACY BY THE NATIONAL BOARD OF TRIAL ADVOCACY
THERE IS NO PROCEDURE IN THE COMMONWEALTH OF VIRGINIA FOR APPROVING CERTIFYING ORGANIZATIONS

005

7010 2780 0003 5272 9078

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OCT 11 2018

Sent To: William A. Hahn II, Esq.
Barnes & Thornburg LLP
Street, Apt. No.; or PO Box No.: 11 South Meridian Street
City, State, ZIP+4: Indianapolis, IN 46204

PS Form 3800, August 2006 — See Reverse for Instructions

PLACE STICKER AT TOP OF ENVELOPE TO THE RIGHT OF THE RETURN ADDRESS, FOLD AT DOTTED LINE

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:
William A. Hahn II, Esquire
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204

9590 9402 2231 6193 3335 12

2. Article Number (Transfer from service label)
7010 2780 0003 5272 9078

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X Ed Maguire
☐ Agent
☐ Addressee

B. Received by (Printed Name) Ed Maguire
C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
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☐ Collect on Delivery
☐ Collect on Delivery Restricted Delivery
☐ Priority Mail Express®
☐ Registered Mail™
☐ Registered Mail Restricted Delivery
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☐ Signature Confirmation™
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005

BARNES & THORNBURG LLP

11 S. Meridian Street
Indianapolis, IN 46204-3535
317-236-1313
317-231-7433 (Fax)

www.btlaw.com

William A. Hahn
Partner
(317) 231-7364
william.hahn@btlaw.com

November 14, 2018

Via United States First Class Mail

Robert W. Mann
Young, Haskins, Mann, Gregory,
McGarry & Wall, PC
400 Starling Ave.
Martinsville, VA 24112

Re: *Susan Cardoza – Claim Regarding Pinnacle Acetabular Cup System*

Dear Mr. Mann:

Thank you for allowing us the opportunity to review the medical records and explant relating to your client Susan Cardoza's claim. The examination of these materials does not indicate that any DePuy products that were implanted in her hip were defective in any respect. Accordingly, DePuy respectfully declines your client's claim.

The records we have received indicate that Ms. Cardoza had a left hip total replacement in 2013. We have received no records relating to that procedure. On June 1, 2016, Ms. Cardoza treated with Dr. Mark Hermann with reports of both right knee and right hip pain. Dr. Hermann diagnosed her with having early osteoarthritis in her right hip. At that time, Dr. Hermann did not recommend a hip replacement procedure due to the early nature of her osteoarthritis. On September 19, 2016, Ms. Cardoza had a follow up with Dr. Hermann at which time she was reporting pain in both her right knee and right hip. Dr. Hermann scheduled her for a follow up appointment to discuss timing of a surgical intervention. On November 11, 2016, she again saw Dr. Hermann to discuss her total hip replacement surgery. At that time, risks and benefits of the procedure were discussed with Ms. Cardoza.

Dr. Hermann performed her right total hip replacement surgery on December 15, 2016. Dr. Hermann elected to utilize a ceramic insert with a ceramic femoral head. We have not received any product stickers for the products Dr. Hermann elected to implant. We also have not received any records identifying the femoral stem or acetabular cup that Dr. Hermann implanted.

Ms. Cardoza had a follow up with Dr. Hermann on December 27, 2016, at which time he noted that she was reporting no difficulties. On March 1, 2017, Ms. Cardoza had another follow up with Dr. Hermann relating to her right hip arthroplasty. At that time, she reported a "crunchy" sensation with an audible noise while bending. She reported that it was not painful. Dr. Hermann examined her and confirmed an audible crunching sound while flexing her hip for

squats. Dr. Hermann determined that he wanted to evaluate her x-rays and recheck her in two weeks. On March 7, 2017, Dr. Hermann saw her again and determined that Ms. Cardoza had sustained a fractured ceramic liner.

Dr. Hermann performed a revision procedure on March 10, 2017. Dr. Hermann noted that the hip fluid he encountered was normal. Dr. Hermann confirmed that the ceramic liner had fractured. He removed the fractured components and the ceramic head. He elected to implant a polyethylene liner and a metal femoral head. We do not have product stickers for the components Dr. Hermann implanted during the revision procedure. Ms. Cardoza saw Dr. Hermann for a follow up appointment on March 23, 2017, at which time he noted that Ms. Cardoza was feeling much better.

With regard to Ms. Cardoza's ceramic insert, DePuy has not identified any anomalies or material defects regarding the insert. Nor were any issues identified with respect to the lot from which the insert came.

Based on the investigation to date, there is nothing demonstrating that any DePuy products implanted during Ms. Cardoza's total hip replacement on her right hip were defective in any respect. Accordingly, DePuy respectfully declines your client's request for compensation. We appreciate your cooperation in allowing us the opportunity to investigate Ms. Cardoza's claim, and extend sincere wishes for her good health in the future. Lastly, please let me know where you would like to have the ceramic insert sent to.

Very truly yours,

William A. Hahn

WAH:alw

Robert W. Mann

From: Robert W. Mann [RWMann@comcast.net]
Sent: Monday, November 19, 2018 3:03 PM
To: 'william.hahn@btlaw.com'
Subject: Susan Cardoza

Dear Mr. Hahn:

I am receipt of your letter dated November 14, 2018, received in today's mail November 19th, 2018. As we discussed on October 30, 2018, we requested that the failed ceramic insert be sent to me at 400 Starling Avenue, Martinsville VA 24112. Of course, assuring the chain of custody is your responsibility. As you know from previous correspondence, as well as our conversation on October 30th , time is of the essence as the applicable statute of limitations runs December 14, 2018.

Your November 14th letter opens and closes with the conclusion that the product was not "defective in any respect". You provide no explanation or basis for this conclusion. DePuy's manufacturing representative ,Matthew Wimbish, without Ms. Cardoza's permission, took possession of the fractured implant on March 10, 2017. So far as we can determine, neither the hospital nor the surgeon purported to give any permission to Mr. Wimbish. That said, the implant belonged to Ms. Cardoza, not the hospital or the surgeon. Under these circumstances, there is at least an implied promise that, in return for DePuy having had the failed product for a year and eight months, DePuy would release to Ms. Cardoza the specifics of any testing done which may have led to the conclusion that the product was not "defective in any respect". Further, I note that your Medical Device Report to the FDA states that the matter is still under investigation, and this has not been finally updated.

In addition to relinquishing physical possession of the fractured implant, we again call on DePuy to provide us with a description of all of the tests done on the failed product; the specific test results; including, but not limited to, raw data. This is essentially the same request that was made by Ms. Cardoza in DePuy's initial notice latter dated April 18,2017. I reiterate, time is of the essence. Please let me have your client's position on this request as soon as possible.

Robert W. Mann
Young, Haskins, Mann, Gregory, McGarry & Wall, PC
400 Starling Ave.
Martinsville, VA 24112
(276) 638-2367 (telephone)
(276) 638-1214 (facsimile)

007

CT Corporation

Service of Process Transmittal
12/28/2018
CT Log Number 534649154

TO: Stephanie Youngman
Johnson & Johnson
1 Johnson and Johnson Plz
New Brunswick, NJ 08933-0002

RE: **Process Served in Virginia**

FOR: Medical Device Business Services, Inc. (Domestic State: IN)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Susan O. Cardoza, Pltf. vs. Medical Device Business Services, Inc., etc., et al., Dfts.
DOCUMENT(S) SERVED:	Summons, Complaint, Exhibit(s)
COURT/AGENCY:	Danville City Circuit Courts, VA Case # 590CL1800085000
NATURE OF ACTION:	Product Liability Litigation - Personal Injury - Ceramic-On-Ceramic Total Hip Replacement Prosthesis
ON WHOM PROCESS WAS SERVED:	C T Corporation System, Glen Allen, VA
DATE AND HOUR OF SERVICE:	By Process Server on 12/28/2018 at 10:20
JURISDICTION SERVED :	Virginia
APPEARANCE OR ANSWER DUE:	Within 21 days after such service
ATTORNEY(S) / SENDER(S):	Robert W. Mann Young, Haskins, Mann, Gregory, McGarry & Wall, P.C. Post Office Box 72 Martinsville, VA 24114-0072 276-638-2367
ACTION ITEMS:	CT has retained the current log, Retain Date: 12/28/2018, Expected Purge Date: 01/07/2019 Image SOP Email Notification, RA-JJCUS LDSOP RA-JJCUS-LDSOP@its.jnj.com
SIGNED: **ADDRESS:** **TELEPHONE:**	C T Corporation System 4701 Cox Road Suite 285 Glen Allen, VA 23060 804-217-7255

COMMONWEALTH OF VIRGINIA

DANVILLE CIRCUIT COURT
Civil Division
401 PATTON STREET PO BOX 3300
DANVILLE VA 24541
(434) 799-5168

Summons

To: MEDICAL DEVICES BUSINESS SERVICES, INC
CT CORP SYSTEM, REG AGENT
4701 COX ROAD
SUITE 285
GLEN ALLEN VA 23060

Case No. 590CL18000850-00

The party upon whom this summons and the attached complaint are served is hereby notified that unless within 21 days after such service, response is made by filing in the clerk's office of this court a pleading in writing, in proper legal form, the allegations and charges may be taken as admitted and the court may enter an order, judgment, or decree against such party either by default or after hearing evidence.

Appearance in person is not required by this summons.

Done in the name of the Commonwealth of Virginia on, Thursday, December 20, 2018

Clerk of Court: GERALD A. GIBSON

by _____ (CLERK/DEPUTY CLERK)

Instructions:

Hearing Official:

Attorney's name: MANN, ROBERT W; ESQ
400 STARLING AVE
P O BOX 72
MARTINSVILLE VA 24112-0072

VIRGINIA: IN THE CIRCUIT COURT FOR THE CITY OF DANVILLE

Susan O. Cardoza,

Plaintiff,

v.

Medical Device Business Services, Inc.
(Formally DePuy Orthopedics Inc.)
700 Orthopaedic Drive
Warsaw, IN 46581

and

Johnson & Johnson Services, Inc.
(Johnson & Johnson)
One Johnson & Johnson PLZ
New Brunswick, NJ 08933
and

DePuy Synthes Sales, Inc.
325 Paramount Drive
Raynham, MA 02767

and

CeramTec GmbH
CeramTec – Platz 1-9
73207, Plochingen
Germany

and

CeramTec North American Corp.
CeramTec Subsidiary, American Headquarters
One Technology Place
Laurens, SC 29360

and

Danville Regional Medical Center, LLC
(d/b/a SOVAH Danville)
103 Powell Ct., Ste 200
Brentwood, TN 37027

and

COMPLAINT
Case No. CL18-850

FILED
2018 DEC 13 PM 12:00
CLERK'S OFFICE
CIRCUIT COURT
DANVILLE, VIRGINIA

LAW OFFICES
YOUNG, HASKINS, MANN,
GREGORY, MCGARRY
& WALL, P.C.
MARTINSVILLE, VA

Spectrum Medical Inc.
109 Bridge Street, Suite 300
Danville, VA 24541

and

Matt Wimbish
Roanoke, Virginia

Defendants

COMES NOW the Plaintiff, Susan Olival Cardoza, by counsel, and respectfully alleges as follows:

PARTIES

1. Plaintiff is a United States citizen residing in Danville, Virginia. (hereafter sometimes, "patient" or "Plaintiff")

2. Defendant, Medical Device Business Services, Inc. is a corporation organized and incorporated in Indiana with its primary place of business in Warsaw, Indiana. This corporation developed, designed, tested, manufactured, distributed and sold the hip implant which is the subject of this lawsuit. (hereafter "DePuy" or " DePuy defendants")

3. Defendant, Johnson & Johnson Services, Inc. is a corporation organized and existing under the law of New Jersey with its primary place of business in New Brunswick, New Jersey. As DePuy's parent company this company was involved in the development, design, testing, manufacturing, distributing and sale of the hip implant which is the subject of this lawsuit. (hereafter "J&J")

4. Defendant, DePuy Synthes Sales, Inc. is a subsidiary, affiliate and/or sister corporation of Johnson & Johnson. Upon information and belief, this company distributed and sold the hip implant which is the subject of this lawsuit. (hereafter "DePuy Sales" or "DePuy defendants")

5. Defendant, CeramTec GmbH, is a company that produces pink-colored ceramic hip implant components sold under the name BIOLOX Delta. This company sells these products to original equipment manufacturers such as, and including, the DePuy and J&J defendants. The DePuy and J&J defendants incorporate BIOLOX Delta products into hip implant systems that DePuy and J&J in turn sells to hospitals and orthopedic surgical groups for use by surgeons in orthopedic surgeries. (hereafter "CeramTec")

Law Offices
Young, Haskins, Mann,
Gregory, McGarry
& Wall, P.C.
Martinsville, VA

6. Defendant, CeramTec North American Corp. is a subsidiary or affiliate corporation of CeramTec GmbH having a United States presence in Laurens, South Carolina. Upon information and belief, this company distributes and sells CeramTec hip implant products, including the products sold herein, in the United States. (hereafter "CeramTec Sales" or "CeramTec defendants")

7. Defendant, Danville Regional Medical Center, is a subsidiary of LifePoint Health Systems whose primary place of business is Brentwood, Tennessee. This defendant operates the hospital in Danville, Virginia. (hereafter "Hospital")

8. Defendant, Spectrum Medical Inc. is a healthcare provider in the Commonwealth of Virginia whose services include, among other things, orthopedic surgery. (hereafter "Spectrum")

9. Defendant, Matt Wimbish, at all pertinent times, was a manufacturer's representative for the DePuy defendants. At all pertinent times, this defendant resided in Virginia. (hereafter "Wimbish")

JURISDICTION AND VENUE

10. This Court has personal jurisdiction over the DePuy and J&J defendants because they are authorized to do business and in fact do business in this state. These defendants and CeramTec have sufficient minimum contacts with this state and otherwise purposefully avail themselves of the markets in this state through the promotion, marketing, and sale of its hip implant products in Virginia. This Court has Long-arm jurisdiction over CeramTec pursuant to Virginia Code § 8.01-328.1, paragraphs 2, 4, and 5.

11. This Court has subject matter jurisdiction over this action, pursuant to VA. Code §17.1-513.

12. The proper venue for this case lies in Danville inasmuch as the Hospital and Spectrum, have principle places of business located in Danville, Virginia.

FACTS

13. Sometime prior to December 15, 2016, the J&J and DePuy defendants, and the CeramTec defendants, developed, designed, tested, manufactured, distributed, sold, and placed in the stream of commerce a ceramic-on-ceramic total hip replacement prosthesis which is the subject of this lawsuit. Said prosthesis is known as CERMAX Ceramic Total Hip System and is specifically identified by the package "sticker" labeling attached. (Exhibit A). This prosthesis will be hereafter referred to as "the product".

14. On or about December 15, 2016, the defendant Hospital and/or the Spectrum defendant resold the product to the patient, and her surgeon implanted the product in her body during a total hip replacement.

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15. The hip is a ball-and-socket joint, where the ball is the femoral head and the socket is formed by the acetabulum.

16. In a total hip replacement, surgeons remove damaged biological material and implant prosthetic components.

17. In the product which is the subject of this lawsuit, the liner which is part of the acetabulum component, and the femoral head were made of ceramic material by CeramTec.

18. In the product which is the subject of the lawsuit, the ceramic femoral head and liner were manufactured and placed in the stream of commerce by the CeramTec. These component parts were sold to the J&J and DePuy defendants and were used and relied upon in the manufacture and sale of the product.

19. On or about December 15, 2016, the patient underwent a total hip replacement procedure at the Hospital.

20. At the time and place aforesaid, the product was implanted in the patient's body by a surgeon who was an employee and agent of Spectrum, acting within the scope of his employment, authority and agency. (hereafter "surgeon")

21. On or about March 3, 2017 the patient presented to Spectrum reporting "a squeaking pain and increasing pain of her hip". It appeared to Spectrums' orthopedic clinician "that the acetabular liner has displaced completely and is rotated".

22. On or about March 7, 2017, the patient presented again to her original surgeon, at Spectrum, with continued history of increasing hip pain making it even difficult to sleep. Her surgeon concluded that there had been "a fracture of the ceramic liner".

23. After physical examination and x-ray imaging, the surgeon determined that the product had probably malfunctioned and emergent revision surgery was indicated.

24. On or about March 10, 2017, the patient presented to the Hospital for emergent revision surgery.

25. Prior to surgery, the patient specifically told her surgeon that she would like to have the parts that were to be removed from her body, and requested that said explants be given to her. Her surgeon agreed that the product would be preserved and given to the patient.

26. During the revision surgery, the surgeon found that the ceramic liner had indeed "fractured in multiple planes" and that sharp dangerous fragment shards had been deposited in the patient's body.

27. During the revision surgery, the surgeon removed the ceramic head and shattered ceramic liner, and replaced said components with non-ceramic implants.

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28. To the best of the surgeon's ability he removed the shattered ceramic fragments and shards. However, despite his best efforts, all of the dangerous shards could not be removed.

29. At the time of the revision surgery, while the patient was under general anesthesia, the defendant Wimbish took possession of the shattered pieces of the ceramic liner which had been removed from the patient's body. In so doing, defendant Wimbish was acting within the scope of his employment and/or agency with the DePuy defendants, and his actions were in furtherance of DePuy's interests.

30. The patient paid for the product. When it was implanted in her body on or about December 15, 2016, the product thereafter belonged to her.

31. Neither DePuy nor defendant Wimbish had the patient's permission, authorization, or consent to take possession of the product.

32. The ceramic head was retained by the hospital. By report, the head was cracked, but not shattered.

33. Since March 10, 2017, the patient has been hospitalized on several occasions for hip related complications stemming from her original surgery. The patient has undergone a second revision surgery at an outside hospital. Subsequent treating physicians have been unable to remove the remaining dangerous shattered ceramic fragment shards from her body.

34. Upon information and belief, the shattered fragments taken by defendant Wimbish have been examined, inspected, and tested in an attempt to determine the root cause of the failed prosthesis. It is believed, and therefore averred and alleged, that examination, inspection and testing of the failed product took place in Warsaw, Indiana and in Leeds, England. The chain of custody is unknown.

35. On April 7, 2017, lawyers then representing the patient sent a Preservation of Evidence/Spoliation notice letter to the Hospital. (Exhibit B).

36. Upon information and belief, the hospital still has physical possession of the cracked femoral head, which was removed from the patient's body.

37. The hospital has failed and refused to allow the patient to take possession of the femoral head without a "subpoena".

38. On or about April 18, 2017, lawyers then representing the patient sent a Preservation of Evidence/Spoliation notice letter to the DePuy defendants. (Exhibit C).

39. Despite follow-up written requests on July 24, 2017, November 6, 2017 and February 5, 2018, and numerous telephone calls to DePuy, there was no meaningful response

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whatsoever except to identify the attorney who was handling the matter for DePuy until November 23, 2018.

40. Subsequently, despite continuing requests for the results of DePuy's examination, testing, and inspection of the ceramic liner, DePuy has failed and refused to make this information available to the Plaintiff.

41. On or about November 23, 2018, the DePuy defendants belatedly caused to be delivered to the Plaintiff's agent what purported to be the shattered components of the Plaintiff's explanted prosthesis. The fragments and shattered pieces were in an unsecured Ziploc bag with insufficient and confusing identifying information.

42. The DePuy defendants knew that, under these circumstances, at this point in time, it would be virtually impossible for the Plaintiff to determine with reasonable certainty the root cause of her injuries and damage.

43. The product is a Class III medical device which, by definition, is a product having an unreasonable risk of serious bodily injury or death unless approved manufacturing processes are strictly adhered to.

44. During clinical trials, required by the FDA, before marketing the product, the DePuy defendants reported isolated ceramic liner "fracture" to have been observed on x-ray only after more than 18 months of duration of implantation. Subsequent surveillance and reporting of ceramic line "fracture" have provided similar information.

45. Isolated "fracture" is materially different from a ceramic liner "shattering" into many pieces as occurred in the Plaintiff's hip after less than three months of implantation.

46. It is highly unlikely that a ceramic liner would "shatter", as in this case, if the DePuy defendants, during the manufacturing process, had appropriately followed their own protocol as approved by the FDA.

47. The product was in substantially the same condition when implanted in the patient's body as it was when it left the hands of the defendants.

COUNT I
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY BY DEPUY AND J&J DEFENDANTS

48. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

49. At all times relevant to this action, all defendants were merchants with regard to the product at issue.

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50. Said defendants impliedly warranted that the product they either designed, selected, produced, inspected, tested, manufactured, packaged, marketed, distributed, and sold was merchantable under applicable law.

51. Said defendants breached this implied warranty of merchantability because the product was defective, unreasonably dangerous, and neither fit, suitable nor safe for the ordinary purposes for which it was intended, and would not pass without objection in the industry in which it was sold. In this, among other things, in manufacturing the product the DePuy defendants failed to adhere to FDA approved processes and procedures causing a manufacturing defect. Stated differently, the product the patient received was not the product approved by the FDA because defendants did not adhere to FDA manufacturing requirements.

52. As a direct and proximate result of these defendants having breached an implied warranty of merchantability, the patient has suffered injuries and damages described in this Complaint.

COUNT II
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE BY DEPUY AND J&J DEFENDANTS

53. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

54. At all times relevant to this action, these defendants knew or had reason to know that purchasers of the product would be using it in connection with hip replacement, thus relying upon their representation that it was reasonably safe for this particular purpose.

55. Said defendants impliedly warranted that the product they either designed, selected, produced, inspected, tested, manufactured, packaged, marketed, distributed, and sold was fit for the purpose of hip replacement when in fact, it was not.

56. Said defendants breached this implied warranty of fitness for a particular purpose because the product was defective, unreasonably dangerous, and neither fit, suitable nor safe for the particular purpose for which it was manufactured and sold. In this, among other things, in manufacturing the product the DePuy and J&J defendants failed to adhere to FDA approved processes and procedures causing a manufacturing defect. Stated differently, the product the patient received was not the product approved by the FDA because defendants did not adhere to FDA manufacturing requirements.

57. As a direct and proximate result of these defendants' having breached an implied warranty of fitness for a particular purpose, the patient has suffered injuries and damages described in this Complaint.

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COUNT III
BREACH OF IMPLIED WARRANTY MERCHANTABILITY BY CERAMTEC

58. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

59. At all times relevant to this action, all defendants were merchants with regard to the product at issue.

60. Said defendants impliedly warranted that the product they either designed, selected, produced, inspected, tested, manufactured, packaged, marketed, distributed, and sold was merchantable under applicable law.

61. Said defendants breached this implied warranty of merchantability because the product was defective, unreasonably dangerous, and neither fit, suitable nor safe for the ordinary purposes for which it was intended, and would not pass without objection in the industry in which it was sold.

62. As a direct and proximate result of these defendants having breached an implied warranty of merchantability, the patient has suffered injuries and damages described in this Complaint.

COUNT IV
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE BY CERAMTEC

63. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

64. At all times relevant to this action, these defendants knew or had reason to know that purchasers of the product would be using it in connection with hip replacement, thus relying upon their representation that it was reasonably safe for this particular purpose.

65. Said defendants impliedly warranted that the product they either designed, selected, produced, inspected, tested, manufactured, packaged, marketed, distributed, and sold was fit for the purpose of hip replacement when in fact, it was not.

66. Said defendants breached this implied warranty of fitness for a particular purpose because the product was defective, unreasonably dangerous, and neither fit, suitable nor safe for the particular purpose for which it was manufactured and sold.

67. As a direct and proximate result of these defendants' having breached an implied warranty of fitness for a particular purpose, the patient has suffered injuries and damages described in this Complaint.

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COUNT V
FAILURE TO WARN BY CERAMTEC

68. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

69. These defendants knew, or had reason to know, that the product would be utilized by orthopedic surgeons and patients in the exact fashion as set forth in this Complaint.

70. These defendants knew, or had reason to know, that without more explicit warnings to surgeons and patients there was an unreasonable risk of breaking, fracture, and shattering of the product. In spite of the unreasonable condition of said product without more explicit warnings, these defendants failed to provide adequate warnings and instructions to patients and surgeons.

71. As a direct and proximate result of these defendants' having failed to warn, the patient has suffered injuries and damages described in this Complaint.

COUNT VI
BREACH OF EXPRESS WARRANTIES BY CERAMTEC

72. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

73. These defendants made certain expressed warranties which falsely minimized the products propensity to break, fracture, and shatter. Among other things, theses defendants misleadingly characterized the product as being comparable to steel in hardness.

74. The patient's surgeon, and indirectly the patient, relied upon this type of expressed warranty to the patient's detriment.

75. These defendants breached their expressed warranties in that the product did not conform to the warranties made by these defendants.

76. As a direct and proximate result of these defendants' having breached the expressed warranty, the patient has suffered injuries and damages described in this Complaint.

COUNT VII
SPOLIATION BY DEPUY AND J&J DEFENDANTS

77. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

78. Ceramics are inherently vulnerable to breakage, fracture, and shattering. Although improvements in materials engineering had greatly reduced fracture rates in ceramic

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femoral heads at the time of the patient's surgery, concerns still existed for ceramic liners at this point in time.

79. Knowing these concerns, commencing with the wrongful conversion of the patient's explanted shattered component, and unauthorized analysis use of the patient's medical records, these defendants embarked on a course of conduct intended and designed to conceal the results of their investigation and testing thereby frustrating, and depriving the patient of her right and opportunity to prove a cause of action for products liability. Stated differently, these defendants have suppressed material evidence most likely favorable to the patient. This wrongful course of action continues to this date. In this, among other things, these defendants have thwarted Plaintiff's right to conduct her own investigation as to the cause of her injury and damage; have failed and refused to share with the patient the results of their root cause investigation and testing; and have made use of the Plaintiff's property and confidential records for their own benefit.

80. These defendants have failed to properly and completely report to the FDA the results of their root cause analysis and testing.

81. Where, as here, these defendants have within their control material evidence and do not disclose it, there is an inference, that the evidence, if it were disclosed, would be unfavorable to the defendants.

82. The defendants knew that evidence which has been suppressed, and continues to be suppressed, is crucial to the Plaintiff's underlying action for products liability.

83. As a direct and proximate result of this wrongful course of action (spoliation), the patient has suffered injuries and damages described in this Complaint.

COUNT VIII
WRONGFUL DISCLOSURE OF MEDICAL INFORMATION BY ALL DEFENDANTS EXCEPT CERAMTEC

84. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

85. At all pertinent times, all persons in control of, in possession of, or exercising dominion over the Plaintiff's explanted components and the Plaintiff's medical records were employees or agents of the Hospital defendant and/or the Spectrum defendant, acting within the scope of their employment, agency, and authority. In this, among other things, no such person was pursuing his own ends, or had external, independent or personal motives; such persons were performing a normal function of their assigned service or task; and, the breach of duty occurred during the very thing the person was being paid to do. Breach of duty occurred while engaged in the very thing the person was being paid to do.

86. DePuy is liable under the doctrine of *respondeat superior* (master servant) for all wrongful acts and omissions of such person. The acts and omission of such persons were intended only to serve the purposes of the Hospital and Spectrum.

87. The Hospital and Spectrum Defendants owed a duty to the Plaintiff not to disclose information gained from the Plaintiff during the course of treatment without the Plaintiff's authorization.

88. These Defendants breached this duty by, among other things (a) allowing the Defendant Wimbish to wrongfully take possession of the explanted component (b) violating HIPAA and also HITECH laws and regulations, and common law duties, in disclosing the Plaintiff's confidential medical information to the DePuy defendants.

89. In breaching this duty of care, these Defendants facilitated, were implicit in, and aided and abetted the wrongful conversion and use of the Plaintiff's property and medical records by the DePuy defendants.

90. As a direct and proximate result of this wrongful course of action (disclosure of medical information), the patient has suffered injuries and damages described in this Complaint.

COUNT IX
WRONGFUL CONVERSION BY ALL DEFENDANTS EXCEPT CERAMTEC

91. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

92. In taking possession of the explanted shattered hardware component, the defendant Wimbish and his employer/principle wrongfully exercised and assumed authority over the Plaintiff's property with intent to deprive the Plaintiff of her right and opportunity to determine the cause of her injuries and damage.

93. Thereafter, despite repeated written and verbal requests, the DePuy and J&J defendants wrongfully failed and refused to provide any meaningful information to the Plaintiff or to heed her requests, from March 10, 2017 until November 23, 2018. These defendants to this day have wrongfully failed and refused to provide the results of the root cause analysis and testing.

94. The DePuy defendants ratified and approved the wrongful conversion of Plaintiff's property by Defendant Wimbish.

95. By wrongfully converting the Plaintiff's property to their own use, the DePuy defendants, in equity, impliedly promised to share with the Plaintiff the results of their examination, inspection, and testing.

96. The DePuy defendants, having assumed possession of the fractured explants (along with the Plaintiff's confidential medical records) were under a duty to investigate and

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determine the root cause of the product failure and to report their findings to the Food & Drug Administration (FDA) and to the Plaintiff.

97. In addition to the wrongful conversion of the Plaintiff's explanted failed hip component the DePuy Defendants wrongfully acquired the Plaintiff's personal health information (confidential medical records) without the Plaintiff's authorization, permission, or consent.

98. The Hospital and Spectrum Defendants were complicit in, facilitated, and aided and abetted wrongful conversion of the fractured implant. In this, among other things, these defendants allowed the Defendant Wimbish to take possession of the failed explanted component, and leave the premises; and these Defendants, without authorization, delivered to the DePuy Defendants, or allowed DePuy Defendants to take possession of Plaintiff's confidential medical records.

99. As a direct and proximate result of this wrongful course of action (conversion), the patient has suffered injuries and damages described in this Complaint.

COMPENSATORY DAMAGES AS TO ALL DEFENDANTS

100. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

101. As a direct and proximate result of the acts and omissions of the DePuy and J&J defendants, and the CeramTec defendants, as set forth in Counts I, II, III, IV, V, and VI, the Plaintiff has been required to incur medical and related expense in the past, and will require even further such expenses in the future; has suffered in the past, and continues to suffer, and will suffer in the future severe emotional and mental anguish and distress with physical inconvenience and other physical ramifications, all attributable to the aforesaid acts and omissions, breaches of warranties and other actions described in Counts I through VI; the Plaintiff suffered specific direct injury to her person; was caused other serious and permanent injuries about her person internally and externally; was caused excruciating pain and mental anguish; was maimed and disabled; and, was rendered less capable of performing her normal daily tasks all due to her damage.

102. As a direct and proximate result of the spoliation, wrongful disclosure of medical information, and wrongful conversion by all defendants except CeramTec, as set forth in Counts VII, VIII, and IX, the Plaintiff has lost a fair and timely opportunity to prove her underlying products liability claim; has been deprived of her property; and has suffered an invasion of her privacy; and has been otherwise thwarted and frustrated in her attempts to prove the cause of her injury and damage, all of which has caused the Plaintiff great mental anguish and distress.

PUNITIVE DAMAGES AS TO DEPUY AND J&J DEFENDANTS

103. Plaintiff adopts and re-alleges each prior paragraph, where relevant, as if set forth fully herein.

104. The aforesaid acts and omissions attributable to the DePuy and J&J defendants, as set forth in Counts VII, VIII, and IX, constitute willful and wanton conduct; that is, acting consciously in disregard of civil obligations and the Plaintiff's rights, or acting with reckless indifference to the consequences. These defendants conduct and course of action was so willful and wanton that it shows a conscious disregard of the rights of others. There are severe criminal and civil penalties for HIPAA violations. The tort of conversion, as in this case, is tantamount to grand larceny.

WHEREFORE, Plaintiff moves the Court for judgment against the Defendants jointly and severally for compensatory damages in the amount of $2,500,000.00 (Two million five hundred thousand dollars) prejudgment and other interest as may be appropriate, and her cost in this behalf expended; Plaintiff further moves the Court for punitive damages in the amount of $350,000.00 (Three hundred fifty thousand dollars).

A TRIAL BY JURY IS REQUESTED.

Respectfully submitted,

SUSAN O. CARDOZA

By: _____
Of Counsel

Robert W. Mann, Esquire (VSB #07622)
YOUNG, HASKINS, MANN, GREGORY, MCGARRY & WALL, P.C.
Post Office Box 72
Martinsville, VA 24114-0072
Telephone (276)-638-2367
Facsimile (276)-638-1214
Email: RWMann@comcast.net

DO NOT USE ABBREVIATIONS:

I, QD, QOD, trailing zero (1.0mg), µg, lack of leading zero (.1 mg), MS, MSO4, MgSO4

TIME	
1000	REF 1246-03-000 LOT D16081836 APEX™ HOLE ELIMINATOR - PS (01)10603295019688 (17)280731(10)D16081836 2028-07-31 STERILE R QTY 1 DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw IN 46582 1-800-366-8143 REV.#
	REF 1217-31-052 LOT C91788 PINNACLE® 100 ACETABULAR SHELL 100 52mm OD GRIPTION™ (01)10603295010203 (17)260930(10)C91788 STERILE R 2026-09-30 QTY 1 REV.D
	REF 1218-87-652 LOT 8388193 CERAMAX™ Ceramic Insert NEUTRAL 52mm OD 36mm ID (01)10603295012611 (17)210831(10)8388193 STERILE R 2021-08-31 QTY 1 REV.C
	REF 1365-36-310 LOT 8398876 BIOLOX® DELTA CERAMIC FEMORAL HEAD +1.5 36mm DIA 12/14 TAPER (01)10603295033615 (17)210930(10)8398876 STERILE R 2021-09-30 QTY 1 REV.E
	REF 3L92510 LOT 5259977 CORAIL® HIP SYSTEM CEMENTLESS FEMORAL STEM HA COATED 12/14 AMT 135° STANDARD NO COLLAR K2 SIZE 10 (01)10603295168765 (17)201031(10)5259977 STERILE R 2020-10-31 QTY 1 REV.H

Right total hip

FILED
2018 DEC 13 PM 12:00
CLERK'S OFFICE
CIRCUIT COURT
DANVILLE, VIRGINIA

PLAINTIFF'S EXHIBIT
A.
ALL-STATE LEGAL®

USE BLACK INK ONLY

Patient Information/Label

CARDOZA, SUSAN MARIE

Physician's Progress Report

PROGRESS RECORD

DO NOT USE ABBREVIATIONS:

IU, QD, QOD, trailing zero (1.0mg), μg, lack of leading zero (.1 mg), MS, MSO4, MgSO4

TIME	
955	REF 1221-36-462 LOT C20480 STERILE GP 2021-03-31 PINNACLE® ALTRX® POLYETHYLENE ACETABULAR LINER +4 NEUTRAL 36mm ID 52mm OD (01)10603295018488 (17)210331(10)C20480 QTY 1 REV. E Right hip
	REF 1365-51-000 LOT 8391060 STERILE R 2021-09-30 M-SPEC™ METAL FEMORAL HEAD Ø36mm +1.5 12/14 TAPER (01)10603295033912 (17)210930(10)8391060 QTY 1 REV. E
9:30	[illegible handwriting] 9.5

-473-3789

USE BLACK INK ONLY

CORMDM00629560 PNSCAN DM2805732934

LUIS A. ABREU, PLLC

ATTORNEYS AT LAW

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626 North Ridge Street
Danville, Virginia 24543
www.luisabreulaw.com

(434) 791-4677
Fax: (434) 791-4676

April 7, 2017

VIA U.S. Mail and Certified Mail, Return Receipt Requested

Danville Regional Medical Center
142 South Main Street
Danville, VA 24541

FILED
2018 DEC 13 PM 12:00
CLERK'S OFFICE
CIRCUIT COURT
DANVILLE, VIRGINIA

Preservation of Evidence/ Spoliation Notice

RE: Our Client: Susan Olival Cardoza
Address: 172 Graymont Place
Danville, VA 24541
Date of Birth: 12/19/1953
Social Security #: ###-##-0687

Dear Sir/Madam:

Please be advised that we represent Susan Cardoza with respect to her injuries sustained from a failed hip replacement performed on December 15, 2016. Please provide us with a complete copy of your file regarding services rendered to Ms. Cardoza including, but not limited to, office notes, radiology reports, diagnostic reports, disability slips, prescriptions, statement of account with CPT and ICD-9 codes, etc. Please also provide us with copies of all documentation relating to the hip replacement and parts used in the hip replacement surgery. Enclosed is an original of Danville Regional Medical Hospital's Authorization For Release Of Protected Health Information which has been signed by Ms. Cardoza.

This letter is to also put Danville Reginal Medical Hospital on notice that it must preserve all data of any type relating to the claim. Most importantly, all of the hip replacement parts removed during the operation must be preserved. This includes the CERAMAX Ceramic Insert, BIOLOX Delta Ceramic Femoral Head, and any other part that was replaced on March 10, 2017. Please ensure this letter is provided to the appropriate person in your office who is charged with the custody of the above items.

Please do not dispose of any of this material, as I expect that it will be both discoverable and admissible in any litigation that may arise out of this claim. Failure to preserve this material will result in a request for a spoliation instruction at any trial in this matter.

If you are no longer in possession of these parts, please identify who has or took these parts (and their contact information). Please also share the circumstances under which the parts were removed during the second surgery.

STATE LEGAL
PLAINTIFF'S EXHIBIT
B

LUIS A. ABREU
ATTORNEY AT LAW

Thank you for your assistance in this matter. If you have any questions, please do not hesitate to call us at 434-791-4677 during regular business hours.

Very truly yours,

Michael D. Simmons

MDS/lrp

Enclosure

cc: Ms. Susan Olival Cardoza (W/O Enclosure)
(VIA Electronic Transmission and U.S. Mail)

Mark C. Hermann, M.D. (W/O Enclosure)
(VIA U.S. Mail)

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Danville, Virginia 24543
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(434) 791-4677
Fax: (434) 791-4676

April 18, 2017

VIA Certified Mail, Return Receipt Requested, and Electronic Transmission

DePuy Synthes Joint Reconstruction
700 Orthopaedic Drive
Warsaw, IN 46582

FILED
2018 DEC 13 PM 12:00
CLERK'S OFFICE
CIRCUIT COURT
DANVILLE, VIRGINIA

Preservation of Evidence/ Spoliation Notice

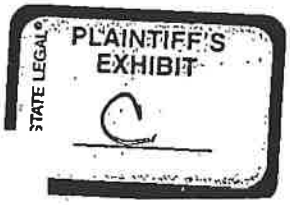
RE: Our Client: Susan Olival Cardoza
Address: 172 Graymont Place
Danville, VA 24541
Date of Birth: 12/19/1953
Social Security #: ###-##-0687

Dear Sir/Madam:

Please be advised that we represent Susan Cardoza with respect to her injuries sustained from a failed hip replacement performed on December 15, 2016. It is requested that you provide us with a complete copy of your file regarding services or products rendered to Ms. Cardoza. Please also provide us with copies of all documentation relating to the hip replacement and parts used in the hip replacement surgery.

This letter is to also put DePuy Synthes on notice that it must preserve all data of any type relating to the claim. Most importantly, all of the hip replacement parts removed during the operation must be preserved. This includes, without limitation, the CERAMAX Ceramic Insert, BIOLOX Delta Ceramic Femoral Head, and any other part that was replaced on March 10, 2017. We have attempted to contact your employee, Richard Fox with Quality Control, whose name was given to us by the office of the treating physician, Dr. Mark C. Hermann. We were notified by Dr. Hermann's office that Mr. Fox had the pieces described above. We were advised that the Case Number is COM-271-588 and the phone number provided to us for Mr. Fox is 1-866-811-9367. We have left several messages at that phone number but have not received any response or call backs, and we are attempting to notify Mr. Fox and DePuy that any and all parts of the hip replacement removed from Ms. Cardoza's hip after the surgery are to be preserved. Please ensure this letter is provided to the appropriate person in your office who is charged with the custody of the above items.

Please do not dispose of any of this material, as I expect that it will be both discoverable and admissible in any litigation that may arise out of this claim. Failure to preserve this material will result in a request for a spoliation instruction at any trial in this matter.



LUIS A. ABREU
ATTORNEY AT LAW

If you are no longer in possession of these parts, please identify who has or took these parts (and their contact information). Please also share the circumstances under which the parts were removed during the second surgery.

Thank you for your assistance in this matter. If you have any questions, please do not hesitate to call us at 434-791-4677 during regular business hours.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan Olival Cardoza (VIA Electronic Transmission and U.S. Mail)

Mark C. Hermann, M.D. (VIA U.S. Mail)

VIRGINIA: IN THE CIRCUIT COURT FOR THE CITY OF DANVILLE

Susan O. Cardoza,

Plaintiff,

v.

Medical Device Business Services, Inc.
(Formally DePuy Orthopedics Inc.)
700 Orthopaedic Drive
Warsaw, IN 46581

and

Johnson & Johnson Services, Inc.
(Johnson & Johnson)
One Johnson & Johnson PLZ
New Brunswick, NJ 08933

and

DePuy Synthes Sales, Inc.
325 Paramount Drive
Raynham, MA 02767

and

CeramTec GmbH
CeramTec – Platz 1-9
73207, Plochingen
Germany

and

CeramTec North American Corp.
CeramTec Subsidiary, American Headquarters
One Technology Place
Laurens, SC 29360

and

Danville Regional Medical Center, LLC
(d/b/a SOVAH Danville)
103 Powell Ct., Ste 200
Brentwood, TN 37027

FIRST INTERROGATORIES, REQUESTS FOR PRODUCTION OF DOCUMENTS, AND REQUESTS FOR ADMISSIONS TO DEPUY DEFENDANTS
Case No. CL18000850-00

Law Offices
Young, Haskins, Mann,
Gregory, McGarry
& Wall, P.C.
Martinsville, VA

and

Spectrum Medical Inc.
109 Bridge Street, Suite 300
Danville, VA 24541

and

Matt Wimbish
Roanoke, Virginia

Defendants

PLAINTIFF'S FIRST SET OF INTERROGATORIES, REQUESTS FOR PRODUCTIONOF DOCUMENTS AND REQUESTS FOR ADMISSIONS TO MEDICAL DEVICE BUSINESS SERVICES, INC., JOHNSON & JOHNSON SERVICES, INC., AND DEPUY SYNTHES SALES, INC.

NOW COMES Plaintiff, Susan O. Cardoza, by counsel, pursuant to Rules 4:8, 4:9 and 4:11 of the Rules of the Supreme Court of Virginia, and propounds the following discovery to the captioned Defendants: Medical Device Business Services, Inc., Johnson & Johnson Services, Inc. and DePuy Synthes Sales, Inc.

DEFINITIONS

To facilitate your answers to this discovery, the terms used herein have the following meanings unless the context requires otherwise.

1. "The product" refers to CERAMAX Ceramic Total Hip System (containing Biolox Delta), more specifically described and identified in the product labeling or product "stickers" attached as Exhibit A to the Complaint filed herein.
2. The "incident in question" refers to the failure of Ms. Cardoza's prosthetic hip which was implanted in her body December 15, 2016.
3. "Explanted liner components" refers to the fractured ceramic liner pieces removed from Ms. Cardoza's body at the time of revision surgery, March 10, 2017. "Explanted head"

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Martinsville, VA

refers to the ceramic head removed from Ms. Cardoza's body at the time of revision surgery, March 10, 2017.

4. "You" or "your" or "DePuy" refers to Medical Device Business Services Inc. (Formally DePuy Orthopedics Inc.), Johnson & Johnson Services Inc., and DePuy Synthes Sales Inc., its successors, predecessors, agents and employees and all other persons acting on behalf of said defendants.

5. "Documents" or "writings of every kind and description" means all written, typed or printed matter and all magnetic or other records or documentation of any kind or description (including, without limitations, letters, correspondence, telegrams, memoranda, notes, records, minutes, contracts, agreements, records or notations of telephone or personal conversations, conferences, interoffice communications, microfilm, bulletins, circulars, pamphlets, photographs, artists' renderings, invoices, tape recordings, computer printouts and work sheets), including, drafts and copies not identical to the originals, all photographs and graphic matter, however produced or reproduced, and all compilations of data from which information can be obtained, and any and all writings or recordings of any type or nature in your actual or constructive possession, custody or control, including those in the possession, custody or control of any and all present or former directors, officers, employees, consultants, accountants, attorneys or other agents, whether or not prepared by you.

6. "Report" means the results of any examination, inspection, testing, or audits performed by the DePuy defendants, or at the direction and request of DePuy defendants by others.

7. The words "describe" or "identify" when referring to a person are meant to request that you set forth the following information: (a) Full name. (b) Present or last known residential address. (c) Present or last known telephone number. (d) Present occupation, job title, employer and employer's address. (e) Occupation, job title, employer and

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Gregory, McGarry
& Wall, P.C.
Martinsville, VA

employer's address at the time of the event or period referred to in each particular Interrogatory. (f) In the case of any person other than an individual, identification of the officer, employee or agent most closely connected with the subject matter of that Interrogatory and of the officer who is responsible for supervising that officer or employee with regard to the subject matter of that Interrogatory.

8. The words "describe" or "identify" when referring to a document, are meant to request that you set forth the following information: (a) The nature (*e.g.*, letter, handwritten note) of the document. (b) The title or heading that appears on the document. (c) The date of the document and the date of each addendum, supplement or other addition or change. (d) Identification of the author and of the signor thereof, and of the person on whose behalf or at whose request or direction the document was prepared or delivered. (e) Identification of the addressee or recipient thereof, if any. (f) The present location of the document, and the name, address, position or title and telephone number of the person or persons having custody.

INTERROGATORIES

1. Identify the person(s) signing and verifying your answers to this discovery. Identify all persons who were contacted in order to answer to this discovery. Identify DePuy's most knowledgeable person regarding the investigation into your complaint file COM-27-588 and the incident in question. Indentify DePuy's most knowledgeable person regarding the chain of custody for the explanted liner component.

ANSWER:

2. Identify all persons involved in the chain of custody pertaining to the Plaintiff's explanted liner components; and, describe any and all precautions used to assure the safety, security and integrity of the explanted liner components. This question is

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intended for you to disclose, in detail, all circumstances regarding possession and handling of the explanted liner components from the time said components left the surgical tray at the Danville hospital on March 10, 2017 until the time said components were sent to 400 Starling Avenue, Martinsville, Virginia by FedEx on November 21, 2018. Include any and all accidental breakage or damage to the explanted liner components after said components came into the possession of Mr. Wimbish.

ANSWER:

3. How many pieces were there of the explanted liner components when Mr. Wimbish took possession of said components at the Danville hospital. How many pieces of the explanted liner components were placed in the FedEx shipment sent to 400 Starling Avenue, Martinsville, Virginia on November 21, 2018? Indentify and describe all documents and writings of every kind and description in support of your answer.

ANSWER:

4. Indentify and describe, with particularity, all examination, inspections, and testing of the explanted liner components including, but not limited to, all testing to determine hardness, elasticity, and propensity to fracture or break.

ANSWER:

5. Indentify and describe, with particularity, all inspection, examination, and testing of the explanted liner components which was specifically done in an effort to determine the root cause of fracture of the explanted liner component in Ms. Cardoza's hip.

ANSWER:

6. Indentify and describe, with particularity, all inspection, examination, testing, and analysis specifically done to determine whether the explanted liner component was manufactured in compliance with the FDA approved protocol for this product.

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Martinsville, VA

ANSWER:

7. Indentify and describe, with particularity, any destructive testing done on the explanted liner component. Include, but do not limit your answer to, any and all chemical analysis for inclusions; any and all chemicals used to sanitize the explanted liner component; and all other chemical or physical alterations of the explanted liner components. How did you assure that there was no deleterious effect as a result of your procedures and analysis?

ANSWER:

8. What is the last known address of Matthew (Matt) Wimbish? Indentify and describe his employment or agency responsibilities with DePuy.

ANSWER:

9. Indentify and describe, with particularity, when, where, and under what circumstances Mr. Wimbish originally took possession of the fractured explanted liner components.

ANSWER:

10. Indentify and describe, with particularity, all witnesses to Mr. Wimbish having assumed possession of the explanted liner components. Indentify all documents, or paper trail pertaining to this acquisition including, but not limited to, Mr. Wimbish's notes and/or reports.

ANSWER:

11. Indentify and describe, with particularity, when, where, and under what circumstances you acquired Ms. Cardoza's medical records. Indentify all witnesses to this acquisition. Indentify all documents, or paper trail pertaining to this acquisition.

ANSWER:

12. Indentify and describe, with particularity, the root cause of Ms. Cardoza's ceramic

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liner failure and the underlying reasons and contributing causes for such failure. Indentify any documents wherever you referred to attempts to determine the root cause.

ANSWER:

13. State whether or not, as a result of the incident in question, there was any corrective action, recommendations or suggestions with regard to manufacture, sale, and/or repossession of ceramic liner components. If so, identify and explain.

ANSWER:

14. If you contend that Ms. Cardoza, or any third party, caused or significantly contributed to the fracture and failure of the ceramic liner, identify the individual and company and set forth the complete basis for your contention.

ANSWER:

15. Prior to receiving notification of representation from undersigned counsel, sent October 10, 2018 (See Exhibit A), state whether or not your file and investigation of Ms. Cardoza's explanted liner component and the incident in question had been completed and closed. If not, what remained to be done? Explain why there had been no previous response to the repeated requests made by Mr. Simmons. (See Exhibit A)

ANSWER:

16. Indentify and describe, with particularity, your quality assurance protocol to assure compliance with FDA PMA approval. Include, but do not limit your answer to, process controls on raw materials or other materials received from CeramTec or others. Include, but do not limit your answer to, protocols with respect to insuring proper hardness, appropriate elasticity, and minimizing propensity for breakage and fracture.

ANSWER:

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Martinsville, VA

17. In connection with your examination, inspection, and testing of the explanted liner components, was any failure analysis performed? If so, what was specifically done and what were the conclusions? For example: (a) Were the components analyzed to assure its composition and microstructure complied with design specifications? If so, explain. (b) Were the liner components assessed in any way to assure compliance with design specifications for strength, toughness, hardness, wear resistance, and propensity to breakage or fracture? If so, explain. (c) Were the fracture surfaces of the explanted liner components examined to determine if the material had defects that could act as stress raisers? If so, explain.

ANSWER:

18. Indentify and describe, all internal and external audits pertaining to the relevant lots from which Ms. Cardoza's prosthesis was produced.

ANSWER:

19. Indentify and describe, all complaints known to you pertaining to the CERAMAX Ceramic Total Hip System (containing Biolox Delta) from 2000 to the present. Include, but do not limit your description to, whether or not the complaints related to fracture of the ceramic liner.

ANSWER:

20. Indentify and describe, by date, jurisdiction, court, and attorneys and deposition all lawsuits against you from the year 2000 to the present pertaining to alleged defects in the CERAMAX Ceramic Total Hip System (containing Biolox Delta).

ANSWER:

21. If your response to any of the following request for admissions is anything other than an unqualified admission, state in detail and explain the basis for your response and identify all witnesses and documentation which justify your refusal to admit.

ANSWER:

Requests For Production Of Documents

1. Produce DePuy's file pertaining to case COM-27-588, omitting nothing.

RESPONSE:

2. Produce all documents and correspondence, of every kind and description, pertaining to the incident in question. Include, but do not limit your answer to, all correspondence to and from:

a. Other defendants in this lawsuit

b. FDA

c. Internal correspondence

d. Outside consultants

RESPONSE:

3. Produce all reports, memorandums, results, or analysis pertaining to all testing, examination, and inspection of Ms. Cardoza's explanted liner components.

RESPONSE:

4. Produce all findings and non-compliance reports from internal and external audits regarding the lots involved in interrogatory 18.

RESPONSE:

5. Produce your file (personnel file or the like) for Matthew (Matt) Wimbish.

RESPONSE:

6. Produce all writings, of every kind and description, authored or made by Mr. Wimbish in connection with the incident in question.

RESPONSE:

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7. Produce all writings, of every kind and description, sent to Mr. Wimbish by employees or agents of any of the DePuy or J&J defendants in connection with the incident in question.

RESPONSE:

8. Produce any notice letters, correspondence, or writings, of every kind and description, to and from any of the DePuy/J&J defendants and to and from the CeramTec defendants.

RESPONSE:

9. Produce all micrographs, and imaging, of every kind and description, done in connection with investigation, examination and testing of the explanted liner components. Include all indentifying data pertaining to the imaging produced.

RESPONSE:

10. Produce all of your policies, protocols, or procedures pertaining to repossession or taking possession of explanted prosthesis after revision surgery.

RESPONSE:

11. Produce all policies, procedures, or protocols concerning compliance with FDA approved requirements for the products.

REPONSE:

12. Produce a Privilege Log pursuant to Virginia Code § 4:1 (a) (6) (i) indentifying any information, or requested information, in this discovery for which you claim privilege.

RESPONSE:

13. Produce all documentation in support of your conclusion or assertion in Exhibit A (Hahn letter) that Ms. Cardoza's implanted hip was not defective in any way.

RESPONSE:

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Martinsville, VA

14. Produce all documents and correspondence, of every kind and description, concerning or pertaining in any way to your attempts to acquire, and acquiring, Ms. Cardoza's medical records.

RESPONSE:

15. Produce all documents and correspondence, of every kind and description, concerning or pertaining in any way to your attempts to acquire, and acquiring, Ms. Cardoza's explanted head.

RESPONSE:

16. Produce all documents and correspondence, of every kind and description, concerning or pertaining in any way to your attempts to acquire, and acquiring, Ms. Cardoza's explanted liner components.

RESPONSE:

17. Produce all documents, related to or in any way concerning the chain of custody of the explanted liner components.

RESPONSE:

18. Produce all documents indentified in answers to the preceding interrogatories and/or consulted, used, and/or relied upon in preparing answers to this discovery.

RESPONSE:

Requests For Admissions

1. Admit the authenticity and genuineness of correspondence in Exhibit A between agents for DePuy and agents for Ms. Cardoza.

RESPONSE:

2. Admit that, prior to and on the date of the incident in question, it was the custom and practice of DePuy to take possession if possible, or at least seek possession, of all failed implants after revision surgery.

REPSONSE:

3. Admit that, in the past, in keeping with the aforesaid practice DePuy has compensated surgeons financially for acquiring the patient's consent and authorization to release explanted components to DePuy.

RESPONSE:

4. Admit that your acquisition, possession of, and testing of the explanted components was I the ordinary course of business.

REPSONSE:

5. Admit that your acquisition, possession of, and analysis of Ms. Cardoza's medical records was in the ordinary course of business.

REPONSE:

6. Admit that your creation and maintenance of Complaint File COM-27-588 was in the ordinary course of business.

RESPONSE:

7. Admit that, neither DePuy, nor Mr. Wimbish, had Ms. Cardoza's permission, consent, or authorization for you to take possession of her explanted component(s).

RESPONSE:

8. Admit that, when Mr. Wimbish took possession of Ms. Cardoza's explanted component(s), he was acting in furtherance of DePuy's ends, and had no independent personal motive of his own.

REPSONSE:

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Martinsville, VA

9. Admit that, in connection with the incident in question, Mr. Wimbish was DePuy's agent and acting within the scope of his authority and agency.

REPSONSE:

10. Admit that, at all pertinent times, you knew that you did not have Ms. Cardoza's authorization, permission, or consent to possess and exercise dominion over her explanted hip component.

RESPONSE:

11. Admit that, at all pertinent times, you knew that it was improper and unlawful to possess and exercise dominion over Ms. Cardoza's explanted hip without her authorization, permission, and consent.

RESPONSE:

12. Admit that, at all pertinent times, you knew that you did not have Ms. Cardoza's authorization, permission, or consent to possess and exercise dominion over her medical records.

RESPONSE:

13. Admit that, it is unlikely that Ms. Cardoza's ceramic hip implant would have fractured, in separate pieces, in less than three months of implantation, as in this case, if FDA approved protocols and requirements had been followed.

RESPONSE:

14. Admit that, at all pertinent times, you knew that it was improper and unlawful to possess and exercise dominion over Ms. Cardoza's medical records without her authorization, permission, and consent.

RESPONSE:

Law Offices
Young, Haskins, Mann,
Gregory, McGarry
& Wall, P.C.
Martinsville, VA

Respectfully submitted,

SUSAN O. CARDOZA

By: _____
Of Counsel

Robert W. Mann, Esquire (VSB #07622)
YOUNG, HASKINS, MANN, GREGORY, MCGARRY & WALL, P.C.
Post Office Box 72
Martinsville, VA 24114-0072
Telephone (276)-638-2367
Facsimile (276)-638-1214
Email: RWMann@comcast.net

CERTIFICATE OF SERVICE

I certify that a true and exact copy of the foregoing Plaintiff's First Set of Interrogatories, Requests for Production of Documents and Requests for Admissions was sent by first class mail, postage fully pre-paid, to William A. Hahn, II, Esquire, 11 South Meridian Street, Indianapolis, IN 46204-3535, attorney for DePuy and J&J defendants; Ashley Calkins, Esquire, P.O. Box 72050, Richmond, Virginia 23255-2050 attorney for Danville Regional Medical Center LLC; Spectrum Medical Inc., 109 Bridge St., Suite 300, Danville, Virginia, 24541 and CeramTec GmbH, CeramTec-Platz 1-9, 73207, Plochingen, Germany, on this 17th day of December 2018 to:

_____
Robert W. Mann

EXHIBIT A INDEX

LUIS A. ABREU, PLLC
ATTORNEYS AT LAW

Luis A. Abreu
labreu@luisabreulaw.com

Michael D. Simmons
msimmons@luisabreulaw.com

P. O. Box 1598
626 North Ridge Street
Danville, Virginia 24543
www.luisabreulaw.com

(434) 791-4677
Fax: (434) 791-4676

April 18, 2017

VIA Certified Mail, Return Receipt Requested, and Electronic Transmission

DePuy Synthes Joint Reconstruction
700 Orthopaedic Drive
Warsaw, IN 46582

Preservation of Evidence/ Spoliation Notice

RE: Our Client: Susan Olival Cardoza
Address: 172 Graymont Place
Danville, VA 24541
Date of Birth: 12/19/1953
Social Security #: ###-##-0687

Dear Sir/Madam:

Please be advised that we represent Susan Cardoza with respect to her injuries sustained from a failed hip replacement performed on December 15, 2016. It is requested that you provide us with a complete copy of your file regarding services or products rendered to Ms. Cardoza. Please also provide us with copies of all documentation relating to the hip replacement and parts used in the hip replacement surgery.

This letter is to also put DePuy Synthes on notice that it must preserve all data of any type relating to the claim. Most importantly, all of the hip replacement parts removed during the operation must be preserved. This includes, without limitation, the CERAMAX Ceramic Insert, BIOLOX Delta Ceramic Femoral Head, and any other part that was replaced on March 10, 2017. We have attempted to contact your employee, Richard Fox with Quality Control, whose name was given to us by the office of the treating physician, Dr. Mark C. Hermann. We were notified by Dr. Hermann's office that Mr. Fox had the pieces described above. We were advised that the Case Number is COM-271-588 and the phone number provided to us for Mr. Fox is 1-866-811-9367. We have left several messages at that phone number but have not received any response or call backs, and we are attempting to notify Mr. Fox and DePuy that any and all parts of the hip replacement removed from Ms. Cardoza's hip after the surgery are to be preserved. Please ensure this letter is provided to the appropriate person in your office who is charged with the custody of the above items.

Please do not dispose of any of this material, as I expect that it will be both discoverable and admissible in any litigation that may arise out of this claim. Failure to preserve this material will result in a request for a spoliation instruction at any trial in this matter.

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LUIS A. ABREU
ATTORNEY AT LAW

If you are no longer in possession of these parts, please identify who has or took these parts (and their contact information). Please also share the circumstances under which the parts were removed during the second surgery.

Thank you for your assistance in this matter. If you have any questions, please do not hesitate to call us at 434-791-4677 during regular business hours.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan Olival Cardoza (VIA Electronic Transmission and U.S. Mail)

Mark C. Hermann, M.D. (VIA U.S. Mail)

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Fax: (434) 791-4676

July 24, 2017

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

William A. Hahn, II, Esq.
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204-3535

RE: Our Client: Susan Olival Cardoza

Dear Mr. Hahn:

As you may recall, our firm contacted you about Ms. Susan Cardoza's hip replacement parts that were taken by a DePuy representative and subsequently shipped to the U.K. We have not heard from you since May 5, 2017. We are requesting an update on those parts and any relevant information you may have. It is our belief that any testing by DePuy should have been completed by this time and progress in the analysis of the parts should be well under way.

Please update us as soon as possible. We look forward to hearing from you. If you have any questions, please call us at 434-791-4677.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan O. Cardoza (VIA Electronic Transmission and U.S. Mail)

002

LUIS A. ABREU, PLLC
ATTORNEYS AT LAW

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November 6, 2017

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

William A. Hahn, II, Esq.
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204-3535

RE: Our Client: Susan Olival Cardoza

Dear Mr. Hahn:

As you may recall, our firm represents Ms. Susan Cardoza in connection with the injuries she sustained when her total hip replacement surgery in December of 2016 failed. We have not heard from you since May 5, 2017, regarding the removed parts that were sent to the United Kingdom for testing, although we have requested an update on multiple occasions. Please update us as soon as possible, since we need to move forward. In addition, we are requesting that the removed parts be made available to us, or a representative on our behalf, so that we may make an independent evaluation of those parts. Furthermore, we remind you that all the parts need to be preserved as evidence.

Please update us as soon as possible. We look forward to hearing from you. If you have any questions, please call us at 434-791-4677.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan O. Cardoza (VIA Electronic Transmission and U.S. Mail)

003

LUIS A. ABREU, PLLC
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February 5, 2018

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

William A. Hahn, II, Esq.
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204-3535

RE: Our Client: Susan Olival Cardoza

Dear Mr. Hahn:

As you may recall, we represent Ms. Susan Cardoza in the injuries she sustained when her total hip replacement failed. The purpose of this letter is to give you the opportunity to share with us the reason(s) for the failure of the hip replacement parts. Ms. Cardoza's medical records do not expound upon the reason(s) for the failure, and if you are aware of whether it was a manufacturing defect(s), an incorrect installation, or other error, we hope that you would share with us your position as to any reasons her first two operations were not successful.

Finally, we remind you that all the evidence in this matter must be preserved.

Very truly yours,

Michael D. Simmons

MDS/lrp

cc: Ms. Susan Olival Cardoza
(VIA Electronic Transmission and U.S. Mail)

004

LAW OFFICES

YOUNG, HASKINS, MANN, GREGORY, McGARRY & WALL

A PROFESSIONAL CORPORATION

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ROBERT W. MANN*
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RWMANN@COMCAST.NET

R.R. (JIM) YOUNG, JR.
(1922-1995)

PHONE (276) 638-2367
FAX (276) 638-1214

October 10, 2018

Certified Mail Return Receipt Letter
William A. Hahn II, Esquire
Barnes & Thornburg LLP
11 South Meridian Street
Indianapolis, IN 46204

RE: *DePuy case number: COM-271-588*
*Susan Cardoza, DOB: 12/19/1953, SSN: ***-**-0687*

Dear Mr. Hahn:

We are associated with Luis A. Abreu and Michael D. Simmons representing Ms. Cardoza. We have been retained to file suit in this matter. I am enclosing an updated HIPPA authorization and request.

I am also enclosing the initial notice letter and request dated April 18, 2017, along with self-explanatory correspondence dated July 24, 2017, November 6, 2017, and February 5, 2018. It is my understanding there has been no response.

It is apparent that DePuy took possession of the failed implant on the date of Ms. Cardoza's revision surgery, March 10, 2017. It is our understanding that DePuy subsequently conducted an investigation and appropriate testing to determine the root cause of failure. We assume that an appropriate Medical Device Report was filed with the FDA as required by law. In addition to the information previously requested, this request is for all communications relative to this matter between DePuy and the FDA.

Time is of extreme essence. The applicable statute of limitations requires that appropriate action must be filed on or before December 15, 2018. Accordingly, please let me hear from you at your very first convenience.

Very truly yours,

Robert W. Mann

RWM/hmb
Enclosures
Cc: Michael D. Simmons, Esquire
Luis Abreu, Esquire

*CERTIFIED SPECIALIST IN CIVIL TRIAL ADVOCACY BY THE NATIONAL BOARD OF TRIAL ADVOCACY
THERE IS NO PROCEDURE IN THE COMMONWEALTH OF VIRGINIA FOR APPROVING CERTIFYING ORGANIZATIONS

7010 2780 0003 5272 9078

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Barnes & Thornburg LLP
Street, Apt. No.; or PO Box No. 11 South Meridian Street
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William A. Hahn
Partner
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November 14, 2018

Via United States First Class Mail

Robert W. Mann
Young, Haskins, Mann, Gregory,
McGarry & Wall, PC
400 Starling Ave.
Martinsville, VA 24112

Re: *Susan Cardoza – Claim Regarding Pinnacle Acetabular Cup System*

Dear Mr. Mann:

Thank you for allowing us the opportunity to review the medical records and explant relating to your client Susan Cardoza's claim. The examination of these materials does not indicate that any DePuy products that were implanted in her hip were defective in any respect. Accordingly, DePuy respectfully declines your client's claim.

The records we have received indicate that Ms. Cardoza had a left hip total replacement in 2013. We have received no records relating to that procedure. On June 1, 2016, Ms. Cardoza treated with Dr. Mark Hermann with reports of both right knee and right hip pain. Dr. Hermann diagnosed her with having early osteoarthritis in her right hip. At that time, Dr. Hermann did not recommend a hip replacement procedure due to the early nature of her osteoarthritis. On September 19, 2016, Ms. Cardoza had a follow up with Dr. Hermann at which time she was reporting pain in both her right knee and right hip. Dr. Hermann scheduled her for a follow up appointment to discuss timing of a surgical intervention. On November 11, 2016, she again saw Dr. Hermann to discuss her total hip replacement surgery. At that time, risks and benefits of the procedure were discussed with Ms. Cardoza.

Dr. Hermann performed her right total hip replacement surgery on December 15, 2016. Dr. Hermann elected to utilize a ceramic insert with a ceramic femoral head. We have not received any product stickers for the products Dr. Hermann elected to implant. We also have not received any records identifying the femoral stem or acetabular cup that Dr. Hermann implanted.

Ms. Cardoza had a follow up with Dr. Hermann on December 27, 2016, at which time he noted that she was reporting no difficulties. On March 1, 2017, Ms. Cardoza had another follow up with Dr. Hermann relating to her right hip arthroplasty. At that time, she reported a "crunchy" sensation with an audible noise while bending. She reported that it was not painful. Dr. Hermann examined her and confirmed an audible crunching sound while flexing her hip for

squats. Dr. Hermann determined that he wanted to evaluate her x-rays and recheck her in two weeks. On March 7, 2017, Dr. Hermann saw her again and determined that Ms. Cardoza had sustained a fractured ceramic liner.

Dr. Hermann performed a revision procedure on March 10, 2017. Dr. Hermann noted that the hip fluid he encountered was normal. Dr. Hermann confirmed that the ceramic liner had fractured. He removed the fractured components and the ceramic head. He elected to implant a polyethylene liner and a metal femoral head. We do not have product stickers for the components Dr. Hermann implanted during the revision procedure. Ms. Cardoza saw Dr. Hermann for a follow up appointment on March 23, 2017, at which time he noted that Ms. Cardoza was feeling much better.

With regard to Ms. Cardoza's ceramic insert, DePuy has not identified any anomalies or material defects regarding the insert. Nor were any issues identified with respect to the lot from which the insert came.

Based on the investigation to date, there is nothing demonstrating that any DePuy products implanted during Ms. Cardoza's total hip replacement on her right hip were defective in any respect. Accordingly, DePuy respectfully declines your client's request for compensation. We appreciate your cooperation in allowing us the opportunity to investigate Ms. Cardoza's claim, and extend sincere wishes for her good health in the future. Lastly, please let me know where you would like to have the ceramic insert sent to.

Very truly yours,

William A. Hahn

WAH:alw

Robert W. Mann

From: Robert W. Mann [RWMann@comcast.net]
Sent: Monday, November 19, 2018 3:03 PM
To: 'william.hahn@btlaw.com'
Subject: Susan Cardoza

Dear Mr. Hahn:

I am receipt of your letter dated November 14, 2018, received in today's mail November 19th, 2018. As we discussed on October 30, 2018, we requested that the failed ceramic insert be sent to me at 400 Starling Avenue, Martinsville VA 24112. Of course, assuring the chain of custody is your responsibility. As you know from previous correspondence, as well as our conversation on October 30th , time is of the essence as the applicable statute of limitations runs December 14, 2018.

Your November 14th letter opens and closes with the conclusion that the product was not "defective in any respect". You provide no explanation or basis for this conclusion. DePuy's manufacturing representative ,Matthew Wimbish, without Ms. Cardoza's permission, took possession of the fractured implant on March 10, 2017. So far as we can determine, neither the hospital nor the surgeon purported to give any permission to Mr. Wimbish. That said, the implant belonged to Ms. Cardoza, not the hospital or the surgeon. Under these circumstances, there is at least an implied promise that, in return for DePuy having had the failed product for a year and eight months, DePuy would release to Ms. Cardoza the specifics of any testing done which may have led to the conclusion that the product was not "defective in any respect". Further, I note that your Medical Device Report to the FDA states that the matter is still under investigation, and this has not been finally updated.

In addition to relinquishing physical possession of the fractured implant, we again call on DePuy to provide us with a description of all of the tests done on the failed product; the specific test results; including, but not limited to, raw data. This is essentially the same request that was made by Ms. Cardoza in DePuy's initial notice latter dated April 18,2017. I reiterate, time is of the essence. Please let me have your client's position on this request as soon as possible.

Robert W. Mann
Young, Haskins, Mann, Gregory, McGarry & Wall, PC
400 Starling Ave.
Martinsville, VA 24112
(276) 638-2367 (telephone)
(276) 638-1214 (facsimile)

007

VIRGINIA:

IN THE CIRCUIT COURT FOR THE CITY OF DANVILLE

SUSAN O. CARDOZA, Plaintiff, v. JOHNSON & JOHNSON SERVICES, INC., *et al.* Defendants.	)	Case No. CL 18-850

DANVILLE REGIONAL MEDICAL CENTER, LLC'S DEMURRER

COMES NOW Defendant Danville Regional Medical Center, LLC, d/b/a Sovah Health Danville ("Danville Regional"), by counsel, pursuant to Rule 3:8(a) of the Virginia Rules of Civil Procedure and Va. Code § 8.01-273, and moves this Court to dismiss this action with prejudice:

BACKGROUND

This is an action that arises out of the health care provided to Plaintiff Susan O. Cardoza ("Plaintiff") at Danville Regional. Plaintiff alleges that she underwent a revision surgery, following a right hip replacement procedure. (Comp. ¶¶ 19, 24). Plaintiff alleges that during the revision surgery, the surgeon removed the ceramic liner—a component of the hip implant—which was allegedly shattered and replaced that component with a non-ceramic implant. (Comp. ¶ 27). The ceramic liner was allegedly manufactured by Defendant CeramTec and sold to and by Defendant DePuy Synthes Sales, Inc. ("DePuy"). Defendant Matt Wimbish ("Mr. Wimbish") was allegedly a representative for DePuy. (Comp. ¶¶ 4, 9, and 29). The Complaint provides: "At the time of the revision surgery, while the patient was under general anesthesia, the

defendant Wimbish took possession of the shattered pieces of the ceramic liner which had been removed from the patient's body." (Comp. ¶ 29).

The Complaint includes two allegations against Danville Regional: "wrongful disclosure of medical information" and "wrongful conversion." Both of these claims arise out of Mr. Wimbush's alleged actions. (Comp. ¶¶ 84-99). In regards to the wrongful disclosure of medical information claim, Plaintiff alleges that Danville Regional breached its duty by allegedly allowing Mr. Wimbush to wrongfully take possession of the explanted component, allegedly disclosing Plaintiff's medical information. (Comp. ¶ 88). Similarly, in regards to the wrongful conversion, Plaintiff alleges that Danville Regional allowed Mr. Wimbush to take possession of the alleged failed explanted component and leave the premises, resulting in conversion. (Comp. ¶ 98).

Plaintiff fails to state a claim upon which relief can be granted. Therefore, Danville Regional respectfully requests this Court to grant this Demurrer and dismiss with action against it with prejudice.

ARGUMENT

The Complaint fails to state a claim upon which relief can be granted for several reasons: (1) Plaintiff failed to state a claim of conversion under Virginia law; (2) Plaintiff failed to state a claim for wrongful disclosure of medical information; and (3) Plaintiff failed to state an appropriate claim for damages.

I. Plaintiff failed to state a claim of conversion under Virginia law.

"A person is liable for conversion for the wrongful exercise or assumption of authority over another's goods, depriving the owner of their possession, or any act of dominion wrongfully exerted over property in denial of, or inconsistent with, the owner's rights." *Simmons v. Miller*,

261 Va. 561, 582, 544 S.E.2d 666, 679 (2001). "An action for conversion can be maintained only by the person having a property interest in and entitled to the immediate possession of the item alleged to have been wrongfully converted." *Economopoulos v. Kolaitis*, 259 Va. 806, 814, 528 S.E.2d 714, 719 (2000). "Therefore, to prove conversion, plaintiff must show, by a preponderance of the evidence, a right of possession or ownership of the property at the time of conversion and that defendant converted that property by exercising wrongful dominion and control over it, depriving plaintiff of possession." *Virginia Podiatry Residency Found. v. Hurst*, 61 Va. Cir. 324 (2003).

In the case at bar, the property in question is the ceramic liner that was explanted during the revision surgery. The Complaint does not allege that Plaintiff was entitled to immediate possession of the explant at the time of conversion. It simply includes the conclusory allegation that "[w]hen it was implanted in her body on or about December 15, 2016, the product thereafter belonged to her" and that the product was "resold" to her when it was implanted on that date. (Comp. ¶ 3, 30). This does not establish a right of possession or ownership necessary to state a wrongful conversion claim. *Economopoulos v. Kolaitis*, 259 Va. 806, 814, 528 S.E.2d 714, 719 (2000). Similarly, Plaintiff does not allege that Danville Regional's acts amounted to an exertion of wrongful dominion or control over the explant. Plaintiff underwent the revision surgery at Danville Regional and Danville Regional did not wrongfully convert the materials or substances that are routinely removed in the course of this type of operation. Here, Plaintiff was not entitled to the immediate possession of the explanted hip components and Danville Regional's handing of the explant was lawful and appropriate. In fact, Plaintiff does not allege Danville Regional's possession of the ceramic head component was conversion, but only that codefendants' possession of the shattered ceramic liner explant amounted to wrongful conversion.

II. Plaintiff fails to state a claim for wrongful disclosure of medical information against Danville Regional.

Plaintiff alleges that Danville Regional "owed a duty to the Plaintiff not to disclose information gained from the Plaintiff during the course of treatment without the Plaintiff's authorization." (Comp. ¶ 87). Plaintiff contends that Danville Regional breached this duty by disclosing the Plaintiff's "confidential medical information" to the DePuy defendants by "allowing the Defendant Wimbish to wrongfully take possession of the explanted component." (Comp. ¶88). These allegations do not state a claim for which relief can be granted.

a. Danville Regional did not wrongfully disclose Plaintiff's medical information.

The facts alleged by Plaintiff do not amount to wrongful disclosure. A medical device representative's presence in an operating room is not wrongful disclosure of medical information, when the representative is there as technical support for providing that patient care and treatment. Plaintiff underwent a right hip replacement procedure and revision surgery at Danville Regional. (Comp. ¶¶ 19, 24). 45 CFR 164.506(c)(1) provides that: "A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations." Therefore, Danville Regional is permitted to disclose necessary information to medical device companies and its representative to provide technical support for the patients' procedures and to comply with the obligations of the Food and Drug Administration, among other reasons.

b. Danville Regional is not liable for the alleged actions of Mr. Wimbush.

Mr. Wimbush is allegedly a representative of DePuys and is not and never has been an employee, agent, or servant of Danville Regional. (Comp. ¶¶ 4, 9, and 29). An employer is liable for *employee's* tortious acts under theory of respondeat superior only if acts were within

scope of employment. *Roughton Pontiac Corp. v. Alston*, 236 Va. 152, 155, 372 S.E.2d 147, 149 (1988) (emphasis added). Here, Plaintiff does not allege that Mr. Wimbush is/was an employee of Danville Regional. Thus, Danville Regional is not liable for Mr. Wimbush's alleged tortious acts.

Moreover, the Complaint does not allege any specific actions by employees of Danville Regional. Notably, Plaintiff does not allege that the ceramic head component—which she alleges is in Danville Regional's possession—was wrongly converted. (Comp. ¶ 36). Her conversion claim is limited to the alleged shattered ceramic liner explant. Plaintiff alleges that the disclosure of information and/or misappropriation of the explanted components is/was a result of Mr. Wimbish's alleged actions. (Comp. ¶¶ 88-89, 92, 98). Therefore, Plaintiff failed to state a claim for which relief can be granted against Danville Regional.

If these allegations stated viable claims against Danville Regional, then it would create an impossible environment for providing health care, where hospital systems would be unfairly responsible for any individual who provides services at its facilities—regardless of whether any agent-agency relationship exists—and would prevent individuals from having the necessary information to provide the care and support required to sustain a hospital system.

III. Plaintiff failed to state an appropriate claim for damages.

Plaintiff alleges that the direct and proximate result of the alleged wrongful disclosure of medical information and conversion, she has allegedly "suffered injuries and damages in this Complaint." (Comp. ¶¶ 90, 99). The only allegations against Danville Regional concern Mr. Wimbush's alleged actions during the revision surgery. Thus, Plaintiff's alleged injury and damages associated with the initial hip replacement procedure are not and cannot be directed at Danville Regional.

Plaintiff is claiming damages for "mental anguish and distress." (Comp. ¶ 102). But "where conduct is merely negligent, not willful, wanton, or vindictive, and physical impact is lacking, there can be no recovery for emotional disturbance alone." *Hughes v. Moore*, 214 Va. 27, 34, 197 S.E.2d 214, 219 (1973); *see also Sawyer v. C.L. Pincus, Jr. & Co.*, 83 Va. Cir. 251 (2011) (finding that plaintiff failed to state a claim for emotional distress for defendants' alleged negligent taking of their property, stating "'mental anguish and emotional trauma,' pled alone, are insufficient"). Therefore, Plaintiff did not adequately state an emotional distress claim against Danville Regional.

Plaintiff also failed to plead adequate damages for conversion. "The measure of damages for conversion, when the conversion is complete, is the fair market value of the goods converted at the time and place of the conversion." *DPR Inc. of Virginia v. Dinsmore*, 82 Va. Cir. 451 (2011). However, Plaintiff now possesses the only property that she alleges was wrongly converted. (Comp. ¶ 41). As such, "[t]he measure of damages for trespass to chattels is the "actual damages suffered by reason of loss of [the chattels'] use." *DPR Inc. of Virginia v. Dinsmore*, 82 Va. Cir. 451 (2011). Moreover, the "burden of proving with reasonable certainty the amount of damages and the cause from which they resulted; speculation and conjecture cannot form the basis of the recovery." *Condo. Servs., Inc. v. First Owners' Ass'n of Forty Six Hundred Condo., Inc.*, 281 Va. 561, 577, 709 S.E.2d 163, 173 (2011) (quoting *Carr v. Citizens Bank & Trust Co.*, 228 Va. 644, 652, 325 S.E.2d 86, 90 (1985)). Here, any value lost while the ceramic liner explant was not is Plaintiff's possession is merely speculative. Plaintiff failed to plead any appropriate basis of recovery from Danville Regional.

CONCLUSION

WHEREFORE, Defendant Danville Regional Medical Center, LLC respectfully requests that this Court grant this Demurrer and enter final judgment in its favor, to dismiss this action against them from the Court's docket, to award them their costs and attorneys' fees associated with the defense of this action, and for such other and further relief as the needs of this case may require and which this Court deems appropriate.

DANVILLE REGIONAL MEDICAL CENTER, LLC

By 

John T. Jessee, Esq. (VSB No. 18745)
Sarah C. Jessee, Esq. (VSB #92315)
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sarah.jessee@leclairryan.com

Counsel for Danville Regional Medical Center

CERTIFICATE

I hereby certify that this 28th Day of January, 2019 a true copy of the foregoing pleading was e-mailed and mailed to the following:

Robert W. Mann, Esq. (VSB #07622)
YOUNG, HASKINS, MANN, GREGORY, MCGARRY & WALL, P.C.
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Counsel for Plaintiff

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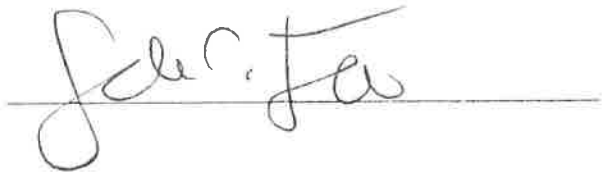
bdevine@williamsmullen.com

Counsel for Medical Device Business Services, Inc.,
Johnson & Johnson Services, Inc.,
and DePuy Synthes Sales, Inc.



VIRGINIA:

IN THE CIRCUIT COURT FOR THE CITY OF DANVILLE

SUSAN O. CARDOZA, Plaintiff, v. JOHNSON & JOHNSON SERVICES, INC., *et al.* Defendants.	)	Case No. CL 18-850

DEFENDANT DANVILLE REGIONAL MEDICAL CENTER, LLC'S MOTION CRAVING OYER

COMES NOW Defendant Danville Regional Medical Center, LLC, d/b/a Sovah Health Danville ("Danville Regional"), by counsel, without waiving or limiting their separately filed Demurrer, request that this Court enter an Order taking oyer of the documents relied on in Plaintiff's Complaint and to permit Danville Regional to file additional responsive pleadings before the Court rules on the demurrer. In support thereof, Danville Regional states as follows:

1. This case arises out a total hip replacement surgery that the Plaintiff underwent at Danville Regional. Following that procedure, the ceramic liner component of the hip implant allegedly shattered, resulting in a revision surgery.

2. Defendant Matt Wimbish, an alleged representative for Defendant DePuy Synthes Sales, Inc., allegedly took possession of the shattered ceramic liner component (the "product") against Plaintiff's wishes during the revision surgery and later provided it to DePuy.

3. In the Complaint, Plaintiff alleges that the product was "resold" to her and that it "belonged" to her when it was originally implanted during the total hip replacement, but the documents on which she relies to support these allegations were not produced.

4. Danville Regional filed a Demurrer on the bases that Plaintiff failed to state a claim of wrongful conversion or wrongful disclosure of medical information against Danville Regional and failure to state an appropriate claim for damages.

5. When ruling on demurrers, the courts consider the facts contained in the pleadings and all reasonable inferences that can be drawn therefrom. Courts also take into account facts contained in or represented by documents brought into a case pursuant to motions craving oyer. Documents produced pursuant to motions craving oyer are incorporated into the pleadings and may be used to amplify the facts alleged in a complaint. *Hale v. Town of Warrenton*, 798 S.E.2d 595, 596 (Va. 2017).

6. A "motion craving oyer requests the court force a party to file an operative document mentioned in the pleadings, but not attached." *Penney v. Brock*, 84 Va. Cir. 459, *1 (Accomack County 2012). "A Defendant may crave oyer of all documents that are necessary to form a basis of Plaintiff's claim, as all essential parts of a pleading are necessary to form an intelligent construction of the pleadings." *Id. See also Ragone v. Waldvogel, Poe, & Cronk Real Estate Group, Inc.*, 54 Va. Cir. 581, 582 (Roanoke 2001).

7. Furthermore, a court may ignore the allegations in the complaint when contradicted by the terms of authentic, unambiguous documents that are properly a part of the pleadings through a motion craving oyer. *EMAC, LLC v. County of Hanover*, 291 Va. 13, 21, 781 S.E.2d 181, 185 (2016).

8. Paragraphs 3 and 30 of the Complaint reference a resale of the product, concluding that Plaintiff owned the product. Plaintiff relies on this conclusion for her wrongful conversion claim and wrongful disclosure of medical information claim against Danville

Regional. The lack of Danville Regional's authority to possess the product is the basis for the claims alleged against Danville Regional in the Complaint.

9. It is necessary before an adequate defense can be made by Danville Regional that the documents referencing who or what entity has the right to use and/or retain the components that were explanted during Plaintiff's revision surgery, which create Plaintiff's legal conclusions to bring the present action, be produced, that oyer be taken of these documents, and that these documents be made *per se* a matter of record as if copied at large in the Complaint. *See D.R. Hall Constr. V. Spotsylvania County Bd. of Supervisors*, 40 Va. Cir. 260, 267 (Spotsylvania County 1996).

10. Danville Regional craves oyer of those documents referencing who or what entity has the right to use and/or retain the components that were explanted during Plaintiff's revision surgery and to include its facts in the initial pleadings over which Danville Regional demurs and from which Danville Regional seeks leave to file additional demurrers or supplement existing demurrers.

11. The documents for which Danville Regional craves oyer includes any and all informed consents signed by Plaintiff which state that Danville Regional is authorized to dispose, use, retain, or donate, at its discretion, any tissues, materials and substances that would normally be removed in the course of the operation that Plaintiff underwent. Specifically, Danville Regional craves oyer over the "Consent to Operation, Treatment Or Other Procedure," which is attached as Exhibit 1.

12. Danville Regional is entitled to have the court consider on demurrer the documents upon which plaintiff relies in her Complaint to state a claim against Danville Regional.

WHEREFORE, Defendant Danville Regional Medical Center, LLC, for the reasons to be presented in oral argument before the Court, respectfully request that the Court enter an Order granting their Motion Craving Oyer and taking oyer of the documents relied upon in the Complaint for attachment thereto and grant Defendants leave to supplement its responsive pleadings.

DANVILLE REGIONAL MEDICAL CENTER, LLC

By _____

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sarah.jessee@leclairryan.com

Counsel for Danville Regional Medical Center

CERTIFICATE

I hereby certify that this 28th Day of January, 2019 a true copy of the foregoing pleading was e-mailed and mailed to the following:

Robert W. Mann, Esq. (VSB #07622)
YOUNG, HASKINS, MANN, GREGORY, MCGARRY & WALL, P.C.
Post Office Box 72
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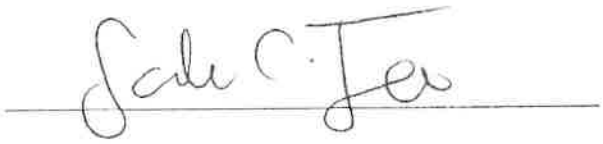
Counsel for Medical Device Business Services, Inc.,
Johnson & Johnson Services, Inc.,
and DePuy Synthes Sales, Inc.



Consent to Operation, Treatment Or Other Procedure

I hereby authorize Dr MARK C HERMANN to perform upon Susan Cardoza (patient)
the following operation, treatment, or other procedure: Right Hip: Revision total hip arthroplasty both components

Procedure Site (check one OR for multiple procedure, indicate sites above):

[X] Right Side [ ] Bilateral [ ] Left Side [ ] Level (for spine) _____

My physician has explained the nature, advisability and purpose of the operation, treatment or other procedure, together with the benefits hoped to result; the risks and the possibility of complications; and alternatives to the operation, treatment or other procedure, if any, and the risks of such alternatives. I understand the explanations that have been given me and I understand that no guarantee is offered as to the results of the operation, treatment or other procedures. The patient has been counseled on the risks and benefits of the proposed procedure. Risks include but are not limited to: bleeding, infection, vessel or tendon/ligament damage, hardware failure, nonunion , mal-union, pain, loss of motion, thrombosis, pulmonary embolism.

Risks/Benefits: The patient has been counseled on the risks and benefits of the proposed procedure. Risks include but are not limited to: bleeding, infection, vessel or tendon/ligament damage, hardware failure, nonunion, malunion, pain, loss of range of motion, thrombosis, pulmonary embolism.

- I understand that some important surgical tasks may be performed by other doctors, assistant surgeons, providers or residents under the supervision of my doctor. These tasks are expected to be: _____

performed by MARK C HERMANN

- I understand that during the course of the operation, treatment or other procedure unforeseen conditions may be found that make an extension of the original operation, treatment or other procedure advisable. I authorize and consent to such extension or other operation, treatment or other procedure as is advisable in the professional judgement of my physician or physicians
- I authorize and consent to the disposal, use, retention or donation by the hospital, at its discretion, of all tissues, materials and substances that would normally be removed in the course of the operation, treatment or other procedure
- Blood Transfusions: I understand that I may need a transfusion of blood or blood products during this operation, treatment or other procedure. My physician has described the risks, benefits and alternatives of this therapy.

[X] I do [ ] I do NOT authorize and consent to the transfusion of such blood products.

[✓] I give my permission for observers to be present during my surgery or procedure for purposes of their medical training or for technical support.

[✓] I consent to the taking and reproduction of any photographs or video during this procedure for medical purposes.

[✓] Sedation may be managed by my physician performing the procedure. Risks and alternatives have been explained to me and I consent to receive sedation as deemed appropriate by my physician.

I hereby certify that I fully understand the above Consent for Surgery and/or Special Procedures. I understand that I should not sign this form if all items have not been explained or answered to my satisfaction. I have been advised that if I desire further or more detailed explanation concerning my diagnosis, recommended and alternative procedures, or possible risks and consequences, it will be given to me by my physician. However, I am satisfied with the explanation given to me.

Mark C Hermann MD Signature of Physician Performing Procedure	3-7-17 Date	1355 Time
Signature of Second Physician (when necessary)	Date	Time
Susan Cardoza Signature of Patient or Legally Authorized Representative	3-7-17 Date	1355 Time
Relationship of Representative	Date	Time
Signature of Witness	Date	Time

Patient Information/Label
Patient Name Susan Cardoza
DOB 12/19/1953

SPEC02

DEFENDANT'S EXHIBIT 1